IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AFFYMETRIX, INC., a Delaware corporation, Plaintiff/Counter-Defendant, v. **ILLUMINA, INC.**, a Delaware corporation, Defendant/Counter-Plaintiff.	Civil Action No.: 04-901 JJF **REDACTED PUBLIC VERSION**

ILLUMINA, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE FIRST AMENDED COMPLAINT

Richard K. Herrmann (#405)
MORRIS, JAMES, HITCHENS
& WILLIAMS LLP
PNC Bank Center, 10th Floor
222 Delaware Avenue
P.O. Box 2306
Wilmington, Delaware 19899-2306
(302) 888-6800

Robert G. Krupka, P.C.
KIRKLAND & ELLIS LLP
777 South Figueroa Street
Los Angeles, California 90017
(213) 680-8400

Mark A. Pals, P.C.
Marcus E. Sernel
KIRKLAND & ELLIS LLP
200 East Randolph Drive
Chicago, Illinois 60601
(312) 861-2000

Attorneys for Illumina, Inc.

Originally filed: January 30, 2006
Public version filed: February 13, 2006

Affymetrix' opposition to Illumina's motion for leave to amend boils down to Affymetrix complaining that the amendment would "complicate" the case for Affymetrix at this stage. Even if that were true, it is not an appropriate ground on which to deny Illumina's motion. Affymetrix cannot claim that Illumina's amendment is "too late" when it was provided to Affymetrix three weeks before the Court's deadline for amending the pleadings, six weeks before the original close of fact discovery, and nine weeks before the current close of fact discovery. Moreover, much of the information in this amended pleading comes from information recently learned in third-party discovery, and information withheld by Affymetrix from discovery. And the amendment does not even change the basic structure of this case -- the proposed inequitable conduct allegations are intertwined with the invalidity allegations that were already part of the case, and the proposed antitrust counterclaim overlaps with the unfair competition counterclaim that was previously pled. This is a timely, proper amendment that must be allowed for Illumina to fully defend itself in this litigation.

Affymetrix also makes a half-hearted argument that the proposed amendments are not sufficiently pled, but this argument fails as well. Illumina has properly alleged specific allegations of inequitable conduct with particularity for all six patents, identifying the specific prior art withheld and the specific circumstances surrounding each allegation. And Illumina's proposed antitrust counterclaim has been pled in expansive detail under both *Walker Process* and other theories of anticompetitive activity. Illumina has identified the relevant market (and sub-markets), Affymetrix' huge

share of that market, and the specific aspects about that market and Affymetrix' conduct that render Affymetrix in violation of the antitrust laws.

Justice requires that Illumina be permitted to file its First Amended Answer and Counterclaims. This motion to amend was filed well in advance of the Court's deadline for amending the pleadings, and contains more-than-sufficient detail supporting the claims alleged. While Affymetrix tries to fabricate a claim of prejudice in attempt to justify denial of Illumina's motion, the truth is that the amendment does not impact the scope of discovery in an appreciable way, and the case can remain on track toward trial in October 2006. Illumina respectfully requests that its motion for leave to file its amended pleading be granted.

I. ILLUMINA'S ANTITRUST COUNTERCLAIM IS PROPERLY PLED AND IS NOT FUTILE

Affymetrix would have this Court apply a pleading requirement to Illumina's antitrust counterclaims that has never heretofore been applied or sanctioned by any court in this country. Affymetrix argues that Illumina's pleading is deficient because it does not allege "who the players are in any purported market" or "what products compete in that purported market" or "whether those products are interchangeable." (Affy Opp. at 3) But such detail, which would be akin to providing a full-blown expert report in a pleading, is not required. Illumina has defined the market(s) as they are defined by persons in the industry -- the DNA (or nucleic acid) microarray market, which is further broken down into the gene expression and genotyping sub-markets. Ironically, ***Affymetrix*** referred to the same market definition in its Complaint in this case. (*See* Complaint at ¶ 9 (referring to "the commercial market for DNA microarrays")). Affymetrix' effort to impose a pleading requirement beyond this information is simply without basis.

The law cited by Affymetrix in support of its argument is inapposite. Affymetrix points to a Third Circuit opinion that states that a court "may" dismiss a pleading if it "alleges a proposed relevant market that ***clearly*** does not encompass all interchangeable substitute products ***even when all factual inferences are granted in plaintiff's favor***." *Queen City Pizza v. Domino's Pizza*, 124 F.3d 430, 436 (3d Cir. 1997) (emphasis added). The insufficient market pled in *Queen City Pizza* was "ingredients, supplies, materials, and distribution services used by and in the operation of Domino's pizza stores," a pleading which did not even account for the "dough, sauce and cups available from other suppliers and used by other companies." *Id.* at 437-38. This is a far cry from the highly-specialized DNA microarray products, and the specific sub-market applications for these products, pled in Illumina's amended counterclaims. Taking all inferences in Illumina's favor, Illumina has certainly properly pled the relevant market.

Notably, Affymetrix does not even mention how Illumina's market definition is deficient. Despite mentioning the principle of interchangeability, Affymetrix does not identify any supposedly-interchangeable goods or services. And Affymetrix' own documents establish that they look at the DNA microarray market in the same way as pled by Illumina.

REDACTED

While Affymetrix can try to wave its hands and imply that there are a host of interchangeable alternatives, the truth of the matter is that Illumina has pled the market as it is viewed in the industry. There is no pleading requirement to create market complexity where none may exist, and Illumina's pleading cannot be rejected on this basis.

Affymetrix' opposition also misses the mark when it seeks to invoke the *Noerr-Pennington* doctrine. Although Affymetrix spends much time debating the "sham litigation" exception to *Noerr*, it is the other well-recognized exception to *Noerr* that applies in this case – *Walker Process* fraud. Affymetrix is asserting patents that were obtained through knowing and willful fraud, and that is a violation of the Sherman Act, in line with *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965). All Affymetrix can say about Illumina's allegations as they pertain to *Walker Process* is that they are "mere failure[s] to cite ... reference[s] to the PTO" with nothing more. (Affy Opp. 10) That is simply not true.

Illumina has pled the necessary elements of a Walker Process claim. Those elements are: (1) that there has been a material representation; (2) that is false or misleading; (3) that was made with intent to deceive; and (4) that the PTO relied upon it – *i.e.*, "but for" the misrepresentation that patent would not have issued. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069-70 (Fed. Cir. 1998).[1] Illumina has pled elements (1)-(3) in connection with the inequitable conduct allegations. (*E.g.*, Tab 1 to DI. No. 163, Amended Answer ¶¶ 19-24, 30-33, 39-44, 50-53, 59-66) Illumina then specifically and further pled element (4):

> The United States Patent and Trademark Office relied on the Affymetrix' inventors and agents to comply with their duty of candor, and the patents-in-suit would not have issued but for their failure to comply with this duty.

---

[1] Note that in the case of fraud upon the PTO, the fifth element identified in *Nobelpharma*, an injury to the PTO, is usually considered automatic when an invalid patent is issued because of the fraud. Thus, the element is generally not discussed. *E.g., In re Spaulding Sports Worldwide, Inc.*, 203 F.3d 800, 807 (Fed. Cir. 2000) (discussing the elements of a *Walker Process* claim in the context of the crime-fraud privilege exception); *General Electric Co. v. Hoechst Celanese Corp.*, 1990 WL 154218, *5 (D. Del. 1990); *Manville Sales Corp. v. Paramount Systems, Inc.*, 1987 WL 16888, *2 (E.D. Pa. 1987); *Union Carbide Corp. v. Dow Chemical Co.*, 619 F. Supp. 1036, 1052 (D. Del. 1985).

(Tab 1 to DI. No. 163, Amended Answer ¶ 69) Illumina additionally pled that Affymetrix' willful fraud upon the PTO was further evidenced and compounded by its attempts to conceal its fraudulent conduct. (*Id.* ¶ 70)

It is true that a showing of *Walker Process* fraud "requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct," and that, unlike inequitable conduct, "a finding of *Walker Process* fraud may not be based upon an equitable balancing of lesser degrees of materiality and intent." *Nobelpharma,* 141 F.3d at 1070-71. But Illumina has properly pled knowing and willful fraudulent conduct by Affymetrix. (*E.g.*, Tab 1 to DI. No. 163, Amended Answer ¶¶ 24, 32, 33, 44, 52, 61, 65) The necessary ***level*** of proof, which admittedly differs in inequitable conduct versus *Walker Process* cases, is irrelevant to the issue of sufficiency of pleading.

Finally, Affymetrix' argument against the other anticompetitive conduct alleged in Illumina's amended pleading is also misplaced. Unlike the allegations of inequitable conduct and *Walker Process* fraud, Illumina's other allegations of anticompetitive conduct are not subject to the particularity requirements of Rule 9(b). *See Midwest Gas Services, Inc. v. Indiana Gas Co.*, 317 F.3d 703, 710 (7th Cir. 2003) ("antitrust plaintiffs need not plead to a heightened level of particularity"); *Twombly v. Bell Atlantic Corp.,* 425 F.3d 99, 108-09 (2d Cir. 2005) ("No heightened pleading requirements apply in antitrust cases."). There can be no doubt that Illumina has put Affymetrix on notice of these allegations of anticompetitive conduct with at least the "short and plain statement" as is required by Rule 8(a).

II. AFFYMETRIX WILL NOT BE UNFAIRLY PREJUDICED BY GRANTING ILLUMINA LEAVE TO AMEND

Although Affymetrix, like any party facing an amended pleading, contends that it will be prejudiced if Illumina's amendment is allowed, the facts simply do not back up this contention. Affymetrix blithely suggests that it will need to undertake "massive expenditures" to deal with Illumina's amended pleading, but does not explain in any detail how that is so. And it is not so.

Affymetrix first ignores the fact that Illumina has, from the beginning of this case, alleged unfair competition under Cal. Bus. Code § 17200 et. seq. It is well established that unfair competition claims under this section can incorporate all of the theories available under Section 2 of the Sherman Act, to the point that California courts look to the Sherman Act case law for guidance. *See Cel-Tech Communications v. Los Angeles Cellular Telephone Co.*, 20 Cal.4th 163, 187 (Cal. 1999) ("When a plaintiff who claims to have suffered injury from a direct competitor's "unfair" act or practice invokes section 17200, the word "unfair" in that section means conduct that threatens an incipient violation of an antitrust law, or violates the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law. . . ."). It is at best disingenuous for Affymetrix to suggest that it now must undertake "massive" amounts of additional effort to deal with the market definition and anticompetitive conduct implicated by Illumina's proposed Sherman Act claim. These fundamental facts have always been a part of this case. They are now simply relevant to an additional claim.

Furthermore, Affymetrix cannot contend that Illumina's inequitable conduct allegations create any new discovery obligations on Affymetrix. Inequitable conduct goes to ***Affymetrix'*** knowledge of prior art and intent to withhold it – information about which

Affymetrix needs no discovery. Moreover, any delay in bringing such allegations rests with Affymetrix. Affymetrix has engaged in a "massive" effort to withhold the discovery, as evidenced by the fact that it just ***last week*** produced 50,000 pages of documents relating in large part to the prior art it withheld from the USPTO.[2] There is no basis for Affymetrix to claim it needs more discovery about allegations relating to its own malfeasance.

Illumina anticipates taking no additional discovery than it was planning to take to prove its patent defenses and unfair competition claims. Affymetrix should similarly require no additional discovery, although it will have had nine weeks from learning of Illumina's amended pleading to take any additional discovery it thinks it needs. Indeed, Affymetrix has already been asking questions to Illumina witnesses (*e.g.*, Illumina CEO Jay Flatley) regarding relative market shares and the state of the DNA microarray market. For Affymetrix to now pretend that this is a new aspect of the case, and one that cannot be fully discovered by the close of fact discovery on February 24, is simply not credible.

III. ILLUMINA'S CLAIMS THAT THE PATENTS-IN-SUIT ARE UNENFORCEABLE ARE PROPERLY PLED WITH PARTICULARITY

Affymetrix entirely ignores the great detail in Illumina's First Amended Answer and Counterclaims in arguing that Illumina has not met the particularity requirement of Rule 9(b). This is not a situation where Illumina has waved its hands that Affymetrix has simply withheld "something" that is "material" from the United States Patent and Trademark Office (USPTO). Nor is it a case where Illumina has alleged

---

[2] **REDACTED**

Affymetrix' hide-the-ball strategy is evidenced by the fact that this massive production was made only after Affymetrix' counsel represented to the Court at the January 12 hearing that there were no more documents left to produce.

Affymetrix has withheld everything under the sun, without details regarding any of it. Rather, Illumina has pled specific prior art, specific information withheld, and the circumstances and proof indicating Affymetrix' knowledge of the respective references. Far from merely reciting the elements of a fraud claim, these detailed allegations clearly meet the standards under Rule 9(b). *See, e.g. Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp.2d 726 (D. Del. 2002) (pleading that put patentee on notice of precise misconduct alleged is sufficient); *France Telecom S.A. v. Novell, Inc.*, 2002 WL 31355255 (D. Del 2002) (pleading that put patentee on notice of title, author, and publication date of alleged prior art is sufficient).

Affymetrix' suggestion that it does not know what prior art it allegedly withheld for certain of the patents-in-suit can only be true through willful disregard of Illumina's pleadings. For each of the bead-related patents – the Pirrung '243 patent and the Fodor '432 patent – Illumina has specifically put Affymetrix on notice of the prior art presentations, posters, and abstracts of Drs. Radoje Drmanac and Radomir Crkvenjakov that describe all of the elements of the asserted claims of these patents. (Tab 1 to DI. No. 163, First Amended Answer, at ¶¶ 31-32, 60-61). Illumina has also provided Affymetrix with claim charts detailing this prior art.[3]

REDACTED

[3] Of course, discovery is continuing, and Affymetrix' concealment of prior art may include additional references. In addition, depositions are scheduled of Drs. Drmanac and Crkvejakov, and others that attended these conferences, in the coming weeks. These depositions should further confirm the information withheld by Affymetrix from the USPTO.

REDACTED

Finally, with respect to the prior litigation documents that Affymetrix withheld from the USPTO, Affymetrix makes the extraordinary claim that Illumina is to be faulted for not more specifically pointing out which documents are most important while Affymetrix has refused to produce any of them. Affymetrix should not be allowed to withhold them on the one hand and complain Illumina has not specifically identified them on the other. Regardless, there is a presumption that ***all*** litigation-related documents are material. *See e.g.*, *ICU Medical Inc. v. Braun Medical Inc.*, 2005 WL 588341 (N.D. Cal. 2005) ("related litigation is material *per se*."); *Daimlerchrysler AG v. Feuling Advanced Technologies, Inc.*, 276 F.Supp.2d 1054, 1063 (S.D. Cal. 2003) (under the MPEP litigation is material *per se*). Accordingly, Illumina's pleadings regarding the litigation cannot be considered defective.

Finally, Affymetrix' contention that Illumina somehow delayed in bringing these allegations has no merit. Just because Illumina may have known about some of the prior art for many months does not mean it was in a position to assert the serious charge of inequitable conduct alleging intentional withholding of this prior art from the USPTO with an intent to deceive. There was no delay. For example, the following discovery was obtained in November and December to allow Illumina to make these allegations:

REDACTED

REDACTED

And, as discussed above, Affymetrix has only begun producing documents related to these allegations, which further establish Affymetrix' intentional fraud on the USPTO. Illumina asserted its allegations of inequitable conduct as soon as it obtained sufficient information to bring these serious charges, but discovery is ongoing and specific details and additional evidence proving its allegations are still being developed. Illumina announced its intention to Amend its Answer and Counterclaims and provided the amendments to Affymetrix three weeks before the Court's deadline for amending the pleadings, six weeks before the original close of fact discovery, and nine weeks before the current close of fact discovery. There is no record of undue delay upon which to base a denial of Illumina's motion.

CONCLUSION

For the foregoing reasons, Illumina requests that it be granted leave to file its First Amended Answer and Counterclaims.

Dated: January 30, 2006

Richard K. Herrmann (#405)
MORRIS, JAMES, HITCHENS
& WILLIAMS LLP
PNC Bank Center, 10th Floor
222 Delaware Avenue
Wilmington, Delaware 19899-2306
(302) 888-6800
rherrmann@morrisjames.com

Robert G. Krupka, P.C.
KIRKLAND & ELLIS LLP
777 South Figueroa Street
Los Angeles, California 90017
(213) 680-8400

Mark A. Pals, P.C.
Marcus E. Sernel
KIRKLAND & ELLIS LLP
200 East Randolph Drive
Chicago, Illinois 60601
(312) 861-2000

Attorneys for Illumina, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the 13th day of February, 2006, I caused to be electronically filed the foregoing document, **REDACTED PUBLIC VERSION OF ILLUMINA, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE FIRST AMENDED ANSWER AND COUNTERCLAIMS,** with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

Jack B. Blumenfeld, Esq.
Maryellen Noreika, Esq
Morris Nichols Arscht & Tunnell
1201 Market Street
Wilmington, DE 19801

Additionally, I hereby certify that on the 13th day of February, 2006 the foregoing document was served via email on the following non-registered participants:

Daniel R. Reed, Esq.
Affymetrix, Inc.
6550 Vallejo Street, Suite 100
Emeryville, CA 94608
510.428.8500
Fax 510.428.8583

/s/ Richard K. Herrmann
Richard K. Herrmann (#405)
MORRIS, JAMES, HITCHENS
& WILLIAMS LLP
PNC Bank Center, 10th Floor
222 Delaware Avenue
P.O. Box 2306
Wilmington, Delaware 19899-2306
(302) 888-6800
rherrmann@morrisjames.com

Attorneys for Defendant ILLUMINA, INC.

EXHIBIT C

EXHIBIT REDACTED

IN ITS ENTIRETY

EXHIBIT D

Westlaw.
Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2002 WL 31355255 (D.Del.)
(Cite as: 2002 WL 31355255 (D.Del.))

H
Only the Westlaw citation is currently available.

United States District Court,
D. Delaware.
FRANCE TELECOM S.A., Telediffusion de France S.A., and U.S. Philips Corp.,
Plaintiffs,
v.
NOVELL, INC., Defendant.
No. 102-437-GMS.

Oct. 17, 2002.

MEMORANDUM AND ORDER

SLEET, District J.

I. INTRODUCTION

*1 On May 17, 2002, the plaintiffs, France Telecom S.A. ("France Telecom"), TéléDiffusion de France S.A. ("TDF"), and U.S. Philips Corp. ("Philips") (collectively "the plaintiffs") filed this action alleging patent infringement of a computer software system for accreditating message signatures. The defendant, Novell, Inc. ("Novell"), filed its Answer and Counterclaim on July 16, 2002 (D.I.7). In its Answer, the defendant asserts ten affirmative defenses, including the affirmative defense of "unclean hands." The plaintiffs move to strike this fourth affirmative defense (D.I.8), and the defendant subsequently moved for leave to file an amended Answer (D.I.12). For the following reasons, the court will deny the plaintiffs' motion and grant the defendant's motion.

II. DISCUSSION

A. Defendant's Motion for Leave to Amend Its Answer

The defendant moves to amend its Answer pursuant to Federal Rule of Civil Procedure 15(a). Rule 15(a) provides that a party may amend its complaint "by leave of court ... and leave shall be freely given when justice so requires." FED. R. CIV. P. 15(a). Leave should be freely granted unless there is an apparent or declared reason for denial, *e.g.*, undue delay, bad faith, or dilatory motive on the part of the movant; undue prejudice to the opposing party; or futility of the amendment. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir.1997). Leave to amend is particularly warranted when pleadings lack the requisite factual specificity for a particular cause of action. *See District Council 47 v. Bradley*, 795 F.2d 310, 316 (3d Cir.1986). Indeed, "[t]he clearest cases for leave to amend are correction of an insufficient claim or defense and amplification of previously alleged claims or defenses." *U.S. v. Teeven*, 1992 WL 683682, at *7 (D.Del. Oct. 27, 1992).

The plaintiffs object to Novell's motion to amend its Answer because, they argue, it is futile, as the amended Answer would remain subject to a motion to strike due to redundancy. For the reasons set out in Part B below, the court finds the two defenses are not redundant, and therefore the amendment is not futile.

Nor would the amendment prejudice the plaintiffs by complicating discovery and confusing issues at trial, as they assert. Indeed, as the plaintiffs imply in their briefs, the more particularized amended Answer will benefit the parties by providing notice of the nature and grounds of the defense and by narrowing discovery and preparation efforts. [FN1] None of the other reasons for denial, such as undue delay, bad faith, or dilatory motive on Novell's part, has been alleged, and the court finds no evidence of such. The defendant's motion for leave to amend the Answer is, therefore, granted.

> FN1. Referring to the defendant's unamended Answer, the plaintiffs asserted: "The unclean hands defense will prejudice plaintiffs if it remains in its present form .... The undefined nature of defendant's current pleading could permit defendant to change the theory of its defense, without putting plaintiffs on notice that this has occurred .... Defendant could also utilize the broad and undefined nature of its 'unclean hands' defense to rationalize 'fishing expeditions' on matters that would otherwise not properly be subject to discovery." Plaintiffs' Opening Brief in Support of Plaintiff's Motion to Strike Defendant's Fourth Affirmative Defense of Unclean Hands at 7-8. These potential problems will be avoided by the amended Answer.

B. Plaintiffs' Motion to Strike Defendant's Fourth Affirmative Defense of Unclean Hands

The plaintiffs move to strike the defendant's fourth affirmative defense of unclean hands pursuant to Federal Rule of Civil Procedure 12(f). Rule 12(f) provides that "the court may order stricken from any pleading any insufficient defense or any redundant ... matter." FED. R. CIV. P. 12(f). Motions to strike affirmative defenses are disfavored. *Proctor & Gamble Co. v. Nabisco Brands, Inc.*, 697 F.Supp. 1360, 1362 (D.Del.1988). When ruling on such a motion, "the [c]ourt must construe all facts in favor of the nonmoving party ... and deny the motion if the defense is sufficient under the law."

*2 In its unamended form, the defendant's fourth affirmative defense reads: "The Complaint and the relief requested therein are barred, in whole or in part, by the doctrine of unclean hands." The plaintiffs contend this articulation is insufficient and redundant. They allege it is insufficient because it provides no notice of the nature of the unclean hands defense and because it does not detail the relationship between the plaintiffs' alleged inequitable conduct and the plaintiffs' claim. [FN2] Even if amended, the plaintiffs object, the defense is redundant, because Novell also asserts the affirmative defense of inequitable conduct. The plaintiffs maintain that these two affirmative defenses share identical elements and standards of proof. If one fails, the plaintiffs contend, so must the other. The court will now address these objections in turn.

> FN2. Although the plaintiffs seem to have withdrawn the insufficiency objections following the defendant's motion for leave to amend the Answer, the court will address the insufficiency objection *vis-a-vis* the amended Answer.

1. Sufficiency per Rule 8

Rule 8 of the Federal Rules of Civil Procedure requires a "short and plain" statement of a claim or defense. FED. R. CIV. P. 8(a) and (b). It is well settled that the Federal Rules intend a liberal pleading standard. *See Leatherman v. Tarrant County Narcotic Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993) (holding that federal courts may not impose a more demanding standard of pleading beyond "the liberal system of 'notice pleading' set up by the Federal Rules"). Indeed, Rule 8 expressly mandates that "[e]ach averment of a pleading shall be simple, concise, and direct." FED. R. CIV. P. 8(e).

The defendant's fourth affirmative defense, as amended, comprises six short paragraphs stating the basis for the unclean hands defense, including the context of the alleged misconduct. This context includes the title, author, and publication date of the reference allegedly withheld by the plaintiffs from the Patent and Trademark Office ("PTO"). The amended affirmative defense clearly meets the threshold sufficiency requirements of Rule 8.

2. Sufficiency Per Rule 9

Rule 9 of the Federal Rules of Civil Procedure requires that all pleadings of fraud or mistake "shall be stated with particularity." FED. R. CIV. P. 9(b). Such averments, however, remain subject to the liberal pleading requirements of Rule 8. *See In re Westinghouse Sec. Litig.*, 90 F.3d 696, 703 (3d Cir.1996); *see generally* 5 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1281, at 520-21 (1990) (pleading with particularity under Rule 9(b) should be done consistently with the general philosophy of Rule 8); 2A JAMES W. MOORE, MOORE'S FEDERAL PRACTICE P 8.13, at 8-58 (2d ed.1995) (the mandate of Rule 8 applies "even where the Rules command particularity, as in the pleading of fraud under Rule 9(b)") (footnote omitted). In the context of alleged inequitable conduct before the PTO during a patent prosecution, "pleadings that disclose the name of the [allegedly withheld] relevant prior art and disclose the acts of the alleged fraud fulfill the requirements of Rule 9(b)." *EMC Corp. v.. Storage Tech. Corp.*, 921 F.Supp. 1261, 1263 (D.Del.1996).

*3 To the extent the defendant's fourth affirmative defense involves fraud and is subject to the particularity requirement of Rule 9(b), this requirement also is satisfied by Novell's amendment. As noted above, the amended Answer discloses the title, author, and publication date of the relevant prior art allegedly withheld from the PTO. Novell's amended fourth affirmative defense suffices "to apprise the other party of what is being alleged in a manner sufficient to permit responsive pleadings" as Rule 9 requires. 5 WRIGHT & MILLER § 1296 (1990).

3. Nexus between the Unclean Hands Defense and Plaintiffs' Claim

The defense of unclean hands requires "an

immediate and necessary relation" between the plaintiff's alleged misconduct and the equity sought by that party. *See Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933) ("[Courts] apply the maxim requiring clean hands only where some unconscionable act of one coming for relief has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation."). Indeed, in the Third Circuit, this nexus is "the primary principle guiding application of the unclean hands doctrine." *New Valley Corp. v. Corporate Prop. Assocs.* 2 & 3, 181 F.3d 517, 525 (3d Cir.1999).

The plaintiffs object to Novell's unamended fourth affirmative defense because, they argue, it fails to disclose any relationship between the alleged inequitable conduct constituting unclean hands, and the patent infringement claim at issue. The amended fourth affirmative defense, however, makes clear this relationship. Novell alleges the defendants knowingly, and with an intent to deceive, failed to disclose relevant and material prior art to the Patent and Trademark Office. If such conduct constitutes unclean hands, it would render the patent unenforceable, and the present infringement action necessarily would fail. *See generally Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933). The relationship between the alleged inequitable conduct on the part of the plaintiffs and the equity sought by them has been made sufficiently clear by Novell's amended Answer.

4. Redundancy

The plaintiffs object to Novell's fourth affirmative defense of unclean hands as redundant because it is indistinguishable from Novell's third affirmative defense of inequitable conduct. The elements and standards of proof for the two defenses are identical, the plaintiffs contend, in the context of non-disclosure of material prior art to the PTO during the procurement of a patent.

The court is unconvinced that the two defenses are "identical," even in the context of non-disclosure to the PTO. The Federal Circuit has defined inequitable conduct as the "failure to disclose material information, or submission of false material information, with an intent to deceive." *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 872 (Fed.Cir.1988). Unclean hands, however, remains a broader defense less amenable to a particular checklist of elements. The doctrine of unclean hands

*4 necessarily gives wide range to the equity court's use of discretion .... It is "not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion." Accordingly one's misconduct need not necessarily have been of such a nature as to be punishable as a crime or as to justify legal proceedings of any character. Any willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim.

Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co ., 324 U.S. 806, 815 (1945) (citation omitted). Although the two affirmative defenses in the instant case may well rest on the same facts and may result in identical outcomes, the defenses themselves are not necessarily identical. Particularly at this early stage in the proceedings and given the disfavor with which motions to strike affirmative defenses are received, the court will allow the fourth affirmative defense to remain, to succeed or fail as it may in the remaining litigation.

III. CONCLUSION

For the aforementioned reasons, IT IS HEREBY ORDERED that:

1. The plaintiffs' motion to strike the defendant's fourth affirmative defense of unclean hands (D.I.8) is DENIED.
2. The defendant's motion for leave to amend its Answer (D.I.12) is GRANTED.
3. The defendant shall file its amended Answer within 10 days of the date of this order.

Not Reported in F.Supp.2d, 2002 WL 31355255 (D.Del.)

END OF DOCUMENT

EXHIBIT E

Westlaw.
Not Reported in F.Supp.
Not Reported in F.Supp., 1990 WL 154218 (D.Del.), 15 U.S.P.Q.2d 1673
(Cite as: 1990 WL 154218 (D.Del.))

▷

Motions, Pleadings and Filings

United States District Court, D. Delaware.
GENERAL ELECTRIC COMPANY, Plaintiff,
v.
HOECHST CELANESE CORPORATION and Celanese Engineering Resins Inc., Defendants.
Civ. A. No. 87-458-JRR.

May 8, 1990.

David A. Anderson, of Potter, Anderson & Corroon, Wilmington, Del. of counsel: William F. Kilgannon, William J. Hone, and Stanley L. Amberg, of Davis, Hoxie, Faithfull & Hapgood, New York City, for plaintiff.

Howard M. Handelman, of Bayard, Handelman & Murdoch, Wilmington, Del. of counsel: John F. Lynch, and Michael Macklin, of Arnold, White & Durkee, Houston, Tex., for defendants.

MEMORANDUM OPINION

ROTH, District Judge.

***1** General Electric Company ("GE") filed this action alleging infringement of U.S. Patent No. 3,953,394 ("the GE patent") against Hoechst Celanese Corporation ("HCC") and Celanese Engineering Resins, Inc. ("CER"). HCC and CER have each counterclaimed for a declaration of noninfringement, invalidity and unenforceability of the GE patent.

I. *FACTS*

During pretrial discovery defendants requested a number of documents from GE that pertain to GE's prosecution of the GE patent in 1976, and to a reexamination of the GE patent in 1985-1986. GE withheld certain of these documents on the grounds of the attorney-client privilege. Defendants moved to compel, arguing 1) that GE's attorney-client privilege is vitiated under the "crime-fraud" exception to the attorney client privilege; and 2) that GE waived the attorney-client privilege by producing evidence that it did not have the requisite "state of mind" to commit fraud on the PTO. Defendants' motions to compel were referred to the United States Magistrate, who, in a Memorandum Opinion dated January 24, 1990, granted defendants' motions to compel in substantial part. Presently before the Court are GE's objections to the Magistrate's decision. For the reasons stated below, the Court treats the Magistrate's Memorandum Opinion as a Report and Recommendation, and adopts the Magistrate's recommendations as modified herein.

A. *The GE Patent*

In order to understand this discovery dispute it is necessary to know something of the chronology of events that surround GE's alleged fraud on the PTO, and something of the invention claimed by GE. The GE Patent was issued in 1976, and reexamined in 1986-1987. GE's original claim was for:

thermoplastic, stable, blended compositions comprising in combination

a. from about 1 to about 99 parts by weight of a poly(ethylene terephthalate) resin [referred to as "PET"] and

b. from about 99 to about 1 part by weight of a poly(1,4-butylene terephthalate) resin [referred to as "PBT"] or a copolyester thereof with a minor amount of an aliphatic or aromatic dicarboxylic acid or an alphatic polyol.

(D.I. 109A, A54) PET and PBT are both polymers, known as polyesters. PET is more common and less expensive than PBT, but because PET crystallizes slowly from the melt, it is brittle when molded. PBT, on the other hand, has superior moldability because it crystallizes more rapidly from the melt than PET, but is more expensive to manufacture. The novelty and objective of the blended compositions claimed by the GE patent is explained in the patent as follows:

Because [PET] is known to crystallize only very slowly from the melt and [PBT] is known to crystallize very rapidly from the melt, in view of the above, it would be entirely unexpected to find that blends of these two resins prove to be highly compatible both on the macro and molecular scale. In other words, these two polyester resins, which should be incompatible on the basis of the wide difference in their rates of crystallization, have, in

fact, been discovered to form a stable alloy ...

*2 It is an object of this invention to improve the moldability of [PET] while improving the properties of [PBT] and to provide compositions having many properties improved over those compositions containing either resin alone.

(D.I. 109A at A53) Thus an important object of GE's invention is to improve the moldability of PET/PBT mixtures. As GE put it: "the invention is predicated on the finding of an unexpected property, namely that the solidified melt of [blended] PET and PBT *will produce a homogeneous molded product.*" (D.I. 109A at A67)

B. *The ABC Experiment--1987*

The GE patent was reexamined in 1986-1987. The Patent Examiner ordered reexamination in light of British Patent No. 1,060,401 ("Kurashiki"), published in 1967, and Belgian Patent No. 747,243, ("Fiber") published in 1970, both of which disclose mixtures of PET and PBT. (D.I. 109A at A66-A67) On reexamination, GE argued to the Examiner that the GE patent was distinguishable from the prior art because those references claimed compounds that contained *copolymers* of PET and PBT, rather than a *blend* of substantially unreacted PET and PBT as called for in the GE Patent. (D.I. 109A at A69) The Examiner rejected GE's argument. He noted that the terminology of the GE patent was not limited to "blends" of PET and PBT alone, and that blends of PET and PBT made under the conditions of the GE's original patent inevitably contain small amounts of block copolymer. (D.I. 109A at A78) The Examiner concluded that:

The claim terminology, when reasonably interpreted, encompasses blended compositions which may comprise various components, including blocked [copolymer] material, as well as the two recited linear polymers. The other components may be in major amounts. The composition blended with all components is a blended composition. Hence, a blended composition as encompassed by the claims may include major proportions of block polymeric materials.

(D.I. 109A at A78) The GE Patent was rejected on November 13, 1987 as "being unpatentable over Kurashiki and Fiber ..." (D.I. 109A at A77)

Shortly after the rejection of the GE Patent, representatives of GE met with the Examiner to discuss limiting the claims under the GE Patent to avoid prior art. GE proposed amending its claims from "comprising" PET and PBT, to "consisting essentially of" PET and PBT. (D.I. 109A at A81) This change in the claim terminology would eliminate copolymer from the claimed blend, thereby avoiding prior art. The Examiner responded that "objective evidence and discussion would be necessary to ... show that what is being eliminated [block copolymer] would *alter the basic nature* of the compositions desired to be claimed." (*Id.*) (emphasis added)

In light of the object of GE's invention--"to improve the moldability of [PET] while improving the properties of PBT," etc.--the Court interprets the Examiner's request to call for evidence that blended compositions of PET and PBT behave differently than compositions of PET and PBT containing significant amounts of block copolymer. GE amended its claims to incorporate the "consisting essentially of" terminology, and conducted an experiment which compared the moldability of the PET/PBT mixture set out in Kurashiki with that of GE's claimed "blend." In March of 1987 GE submitted the following summary of its test results in support of its amended claims:

*3 Sample A-C bars were made by injection molding at a temperature of 170° F with a mold cycle of 30 seconds to produce a bar one quarter inch (1/4 ") thick.

In contrast to the uniformly milky, non-distorted bar of sample C, which bar was prepared from the claimed blend of PET and PBT, Samples A [Kurashiki] and B [Kurashiki/GE mix] were badly distorted and non uniform in that the edges of the bar are semi-transparent and milky only in the center.

* * *

It is urged that the experimental evidence submitted herewith overwhelmingly establishes that a copolymer of PET and PBT present in an amount such as in samples A and B produces a molded product that is unsatisfactory and thus constitutes an alteration of the basic nature of the claimed compositions.

(D.I. 109A at A89-A90) [hereinafter referred to as "the ABC experiment"] Dr. W.F.H. Borman, who supervised the ABC experiment, stated to the Examiner: "The results obtained clearly demonstrate that Samples A & B could not be injection molded to produce a useful product." (Affidavit of Willem F.H.

Borman, D.I. 109A at A97) The conditions of the ABC experiment can be summarized as follows:

```
Barrel Temperature:  500° F
Mold Temperature:    170° F
Cycle Time:          30 sec.
```

Sample	Description	PET Content (%)	Result
A	100% prior art "Kurashiki"	78	Distorted, rubbery, stuck in mold
B	90% "Kurashiki" 10% of 50/50 PET/PBT Blend	75	Distorted, rubbery
C	PET/PBT Blend	38.5	Uniformly milky, non-distorted

(D.I. 109A at A96)

On March 18, 1987, the Examiner confirmed GE's amended claims:

The claims have been amended, narrowed, to exclude any materials which would alter the basic nature of the compositions claimed. It appears from the affidavit of W.F.H. Borman, submitted in support of the amendments, that at least major amounts of block copolymeric material present would alter the basic nature of the blends claimed.

(D.I. 109A at A170)

C. *The German Experiment--1986*

In January, 1986, approximately one year before the reexamination, GE was prosecuting the German counterpart to the GE Patent. In connection with the prosecution of the German patent Dr. Borman performed an experiment ("the German experiment") which compared the moldability of blends containing different ratios of PET and PBT in which there was no block copolymer. (D.I. 109A at A109) Dr. Borman related the results of the German experiment to GE counsel in a letter dated January 21, 1986:

[T]he blends containing 25 and 35% PET yielded well crystallized parts that released easily from the mold without sticking or distortion. The composition containing 55% PET occasionally stuck in the mold and showed distortion as molded. The composition containing 75% PET stuck badly in the mold and was severely distorted due to the rubbery nature of the product as it exited the mold.

*4 (D.I. 109A at A109) The conditions of the German experiment and the results are summarized in the following table:

```
        Barrel Temperature:      500° F
        Mold Temperature:        187° F
        Cycle Time:              20 Sec.
```

Sample	Description	PET Content (%)	Result
A	PET/PBT blend	25	OK
B	PET/PBT blend	35	OK
C	PET/PBT blend	55	Distorted, stuck in mold
D	PET/PBT blend	75	Distorted, rubbery stuck in mold

(D.I. 109A at A109) The German experiment shows that under certain conditions, high concentrations of PET in *blended* compositions produce an unsatisfactory mold product.

The German experiment was conducted in 1986 and the ABC experiment in 1987. Therefore, when Dr. Borman submitted his affidavit and the ABC experiment results to the Examiner in 1987, the German experiment had already taught him that under certain conditions high concentrations of PET in a *blend* similar to the high concentration of PET in the *copolymer* used in the ABC experiment, would produce an unsatisfactory mold. In other words, viewing the two experiments together, it is unclear whether moldability is affected by the presence of copolymer in a mixture or by the level of PET, or by both. Defendants assert that GE's failure to reveal the results of the German experiment to the Examiner in 1987 constitutes fraud on the PTO and vitiates the attorney-client privilege as to numerous documents. The Magistrate agreed with defendants.

II. *DISCUSSION*

A. *Standard of Review*

The parties dispute the standard of review to be applied to the Magistrate's decision. GE claims that the Court must conduct a *de novo* review of the Magistrate's findings, while defendants contend that the Magistrate's ruling must stand unless clearly erroneous or contrary to law. This conflict is engendered by an unfortunate ambiguity in the Court's orders referring these motions to the Magistrate.

The orders referred the case to the Magistrate to "hear, report and recommend." (D.I. 118, 133) This language mirrors the language of 28 U.S.C. § 636(b)(1)(B), which permits district courts to designate a magistrate to report and recommend on case-dispositive motions. Matters referred to a Magistrate under section 636(b)(1)(B) are subject to *de novo* review. *See* 28 U.S.C. § 636(b)(1)(C). The present motions, however, are non-dispositive matters, which ordinarily are referred to the Magistrate to "hear and determine" pursuant to 28 U.S.C. § 636(b)(1)(A). Such non-dispositive matters may be reconsidered only where the Magistrate's order is "clearly erroneous or contrary to law." The Court, the Magistrate, and defendants all assumed that the instant discovery motions had been referred to the Magistrate to "hear and determine." However GE seizes on the "report and recommend" language in the order of reference to argue that the Court must now apply the *de novo* standard of review.

***5** The Court concludes that fairness requires it to conduct a *de novo* review of the issues presented by GE's objections. Having used the language of section 636(b)(1)(B) in the order of reference, the Court will adopt the standard of review mandated by that provision. Accordingly, the Court will read the Magistrate's Memorandum Opinion as though it were a "Report and Recommendation," and conduct "a *de novo* determination of those portions of the report ... to which objection is made." 28 U.S.C. § 636(b)(1).

B. Defendants' Motion to Compel Based on the "Crime-Fraud" Exception to the Attorney-Client Privilege

(1) Legal Standard

Defendants' first motion to compel urges that GE's attorney-client privilege is vitiated under the "crime-fraud" exception to the attorney-client privilege by the fraud GE allegedly perpetrated on the PTO. The legal standard for determining when the shield of the attorney-client privilege may be pierced has been stated as follows:

[W]here, as here, the question is not whether a patent is enforceable, but whether the protective shield of the attorney-client privilege may be pierced, the patentee's conduct must be measured against the traditional standard for fraud. In a patent action, that equates to a *prima facie* showing of (1) a knowing, wilful, and intentional act of misrepresentation or omission before the patent office; (2) that is material; and (3) that the patent office relied upon in deciding to issue the patent.

Union Carbide Corp. v. Dow Chemical Co., 619 F.Supp. 1036, 1052 (D.Del.1985). The Magistrate applied this standard, found that defendants had demonstrated a *prima facie* case of fraud, and ordered GE to produce the documents for *in camera* review.

GE agrees with the legal standard applied by the Magistrate, but objects to the Magistrate's application of the standard to the facts of this case. (D.I. 176 at 2) Indeed, it is beyond doubt in this Court that *Union Carbide* provides the framework for evaluating allegations of crime or fraud in patent cases. However, there is no need to discuss the Magistrate's application of the *Union Carbide* factors here, because the Magistrate ordered *in camera* review of the allegedly privileged documents. [FN1] The showing necessary to trigger *in camera* review is considerably less demanding than that required to show *prima facie* common law fraud.

In *United States v. Zolin*, 109 S.Ct. 2619 (1989), the Supreme Court considered the relationship between *in camera* review and the crime-fraud exception to the attorney-client privilege. The issue presented in *Zolin*

was "whether the applicability of the crime-fraud exception must be established by 'independent evidence' ... or, alternatively, whether the applicability of that exception can be resolved by an *in camera* inspection of the allegedly privileged material." *Zolin*, 109 S.Ct. at 2623. The Court set forth the conditions under which *in camera* review is appropriate as follows:

*6 [A] lesser evidentiary showing is needed to trigger *in camera* review than is required ultimately to overcome the privilege.... Before engaging in *in camera* review to determine the applicability of the crime-fraud exception, 'the judge should require a showing of a factual basis adequate to support a good faith belief by a reasonable person,' *Caldwell v. District Court*, 644 P.2d 26, 33 (Colo.1982), that *in camera* review of the materials may reveal evidence to establish the claim that the crime-fraud exception applies.

109 S.Ct. at 2631.

Therefore the relevant question before the Court on *de novo* review is whether the evidence supports a good faith belief by a reasonable person that *in camera* inspection of GE's allegedly privileged materials may reveal evidence to establish that the crime-fraud exception applies. In other words, could a reasonable person conclude that *in camera* review of GE's documents may lead to evidence of fraudulent intent, materiality, and reliance by the Examiner on that misrepresentation. [FN2] For the reasons outlined below, the Court finds that defendants have made this showing.

(2) Materiality

GE argues that the omission of the German data was not material because the Examiner, both in the final rejection, and in his request for further evidence, did not request GE to show that blends and copolymers behave differently from one another. The Examiner's final rejection of the GE patent was based on the fact that GE's original claim encompassed blended compositions that included copolymers, and consequently was unpatentable over prior art. GE proposed to narrow its claims to eliminate copolymers. In response, the Examiner asked for evidence to show that the removal of copolymers would alter the *basic nature* of the compositions desired to be claimed. This was a fairly broad request. In essence, the Examiner asked GE to show that blends of unreacted polymers behave (mold) differently than blends containing copolymers. [FN3]

Thus the Examiner requested evidence that the presence of copolymers altered the basic nature--the behavior--of the claimed compositions. GE responded with the ABC experiment, showing that samples A and B, which contained significant amounts of prior art copolymer, could not be molded to form a useful product. However, GE failed to disclose that the German experiment showed that blends containing PET in substantially the same proportion as in the copolymer in samples A and B could not be molded either. Thus, as the Magistrate noted, GE knew at the time of the reexamination that "the *absence* or *elimination* of copolymer *does not* necessarily 'alter the basic nature of the compositions desired to be claimed.' " Memorandum Opinion at 16. GE counters that the German experiment is irrelevant to the ABC experiment and to the Examiner's request because the German experiment was conducted under different conditions than the ABC experiment. The German experiment had a different mold temperature and mold cycle than the ABC experiment (20 sec. vs. 30 sec.). GE argues that this difference in "cooking" time means that the German data does not necessarily contradict the ABC data. Moreover, argues GE, the Examiner's request did not require GE to show that all blends of PET and PBT will mold satisfactorily at all combinations of time and temperature within the specified ranges, nor did it require GE to show that the presence of a copolymer always causes a blend to behave differently than a copolymer. GE concludes that the German experiment was not material to the Examiner's request.

*7 GE's materiality argument is strained. GE knew from the German experiment that blends with high proportions of PET did not necessarily mold well. In addition, GE knew that cooking time was a factor in moldability. Therefore, when GE submitted the ABC test to the Examiner with high concentrations of PET in the copolymer and low concentrations of PET in the blend, GE knew that the difference in moldability could have been due to the different proportions of PET, rather than to the crucial distinction between blends and copolymers. Having chosen to submit an experiment with differing ratios of PET, GE should have disclosed to the Examiner that the difference in moldability may have been due to the proportions of PET, rather that the difference between blends and copolymers. In substance then, either the German experiment was material to the Examiner's request, or, if it was not, plaintiff should have indicated to the Examiner that there was a significance in the ABC test, not only in the presence or absence of copolymer, but also in the percentage of PET present in each sample. The Court finds that GE's failure to reveal to the Examiner such information that was relevant to the *basic nature* of the compositions claimed is sufficient to support a good faith belief that *in camera* review of the communications relating to these experiments may reveal further evidence to establish that the crime-fraud exception applies.

(3) Intent

The Court also rejects GE's contention that there is no evidence of fraudulent intent. Dr. Borman and Mr. Mufatti knew of the German experiment at the time it was conducted and one year later they knew of the ABC experiment. These experiments were conducted within a year of each other. *In camera* review of the allegedly privileged communications may uncover further evidence of GE's intent.

(4) Reliance

Reliance is ascertained through application of a "but for" test: "But for the omission or misrepresentation, the claims would not have been allowed." *Union Carbide*, 619 F.Supp. at 1052. The Examiner relied on the ABC experiment to conclude that GE's claimed blends were distinguishable from the prior art. GE's omission of the German experiment was certainly a factor in the Examiner's decision. *In camera* review of GE's allegedly privileged communications may reveal further evidence of GE's understanding of the relationship between the German experiment and the ABC experiment. Such evidence will contribute to defendants' *prima facie* case of common law fraud.

C. *Defendants' Waiver Motion*

Defendants' waiver motion grows out of their "crime-fraud" motion. GE has steadfastly maintained its innocence in the face of defendants' allegations of fraud. To prove its innocence GE offers the testimony of Dr. Borman and Mr. Mufatti, who deny that they recollected the German experiment at the time of the ABC experiment. Borman and Mufatti also assert that, had they remembered it, they would have considered the German experiment irrelevant to the reexamination of the GE patent. Hence, argues GE, there could be no "intent" to defraud the Examiner. Defendants counter that by injecting Borman and Mufatti's state of mind as a defense to the allegations of fraudulent intent, GE has waived its attorney-client privilege with respect to communications which tend to show Borman and Mufatti's knowledge, at the time of the reexamination, of the moldability of high PET blends. The Magistrate agreed with defendants, and concluded that GE had effected a limited waiver of the attorney-client privilege.

***8** The attorney-client privilege is "designed to secure the client's confidence in the secrecy of his communications." 8 *Wigmore on Evidence* § 2327 at 634 (McNaughten Rev.1961). Yet the privilege is not absolute and can be waived. Two basic elements are given play in deciding whether the client has waived the privilege: the client's intent to waive the privilege, which may be implied from the circumstances, and considerations of fairness and consistency. *See International Paper Company v. Fibreboard Corporation*, 63 F.R.D. 88, 92 (D.Del.1974). Fairness prevents a party from disclosing facts beneficial to its position while refusing to disclose, on the grounds of privilege, related facts adverse to its position. *Hercules, Inc. v. Exxon Corp.*, 434 F.Supp. 136, 156 (D.Del.1977).

Here, defendants argue that GE injected Borman and Mufatti's state of mind into this controversy, thereby waiving the privilege for all communications that tend to show their knowledge, during the reexamination, concerning the moldability of high PET blends. GE replies that it was defendants who injected the issue of intent into the controversy by asserting the "crime-fraud" exception to the attorney-client privilege.

This juxtaposition of viewpoints highlights the fact that defendants' waiver claim is a "claim within a claim." In other words, defendants would have no waiver claim unless they had first asserted their crime-fraud claim. GE says, "All we have done is deny intent and point out that there is a lack of intent...." (D.I. 169 at 43) The question becomes what did GE say to "point out" its lack of intent.

A mere denial of intent, without more, is insufficient to constitute a waiver. *See Lorenz v. Valley Forge Insurance Co.*, 815 F.2d 1095, 1098 (7th Cir.1987). On the other hand, when state of mind is an issue in a case, a party should not be permitted to testify about its state of mind at the time allegedly privileged communications occurred, without pointing to nonprivileged evidence to substantiate its claim or allowing the opposition to discover the privileged communications themselves. The evidence submitted by GE is as follows. First, Mr. Mufatti, GE's counsel, testified at deposition:

Q. Did you know at the time you were in the interview with the examiner about [the German experiment] as reflected in [Dr. Borman's Jan. 21, 1986 letter to Mr. Mufatti]?

A. I did not recall that work.

Q. You did not recall it?

A. No.

Q. If you had recalled it, what would you have told the examiner?

A. First of all, I became aware of this letter [five months

ago] during Dr. Borman's deposition. I did not recall this letter at that time or during the interview with the examiner or during the prosecution of the reexamination.

Q. If you had recalled it, do you agree you should have told the examiner about this data?

A. I certainly consider this to be irrelevant to the question of the patentability of the claims.

* * *

***9** Had I remembered this letter at the time or this work, I probably would not have called it to the attention of the Patent Office because I considered this to be irrelevant to the [GE] patent during reexamination.

(D.I. 132A at E66-E67) Dr. Borman testified concerning the same letter:

Q. Dr. Borman, do you have any recollection of the events set forth in this letter?

A. No. I don't have any recollection.

Q. Do you have any recollection of having a meeting or discussion with Mr. Mufatti preparatory to undertaking the work that is reflected in this letter?

A. No, I don't.

* * *

Q. I was discussing with you the fact that one year prior to [the ABC experiment] you had for purposes of the German application supervised [the German experiment], correct?

A. According to the letter I was shown this morning, indeed I had done such work. However, that work was of a totally different nature....

(D.I. 132A at A55-A57)

GE offers this testimony as proof that "Dr. Borman did not recall the 1986 German test at the time of his United States reexamination affidavit a year later. Further, Dr. Borman did not believe the German test was relevant to the [GE] patent," and that Mr. Mufatti considered the German experiment irrelevant to the Examiner's request. (D.I. 176 at 11, 14-15) Yet GE points to no evidence, other than the allegedly privileged communications themselves, which would substantiate these claims.

The only way for defendants to refute these assertions is to examine the privileged communications themselves. In light of GE's affirmative representations regarding Borman and Mufatti's state of mind, and in light of the record reflecting contemporaneous communications between Borman and Mufatti, fairness requires that defendants be allowed to uncover the foundations for GE's assertions. *See Friction Division Products, Inc. v. E.I. DuPont de Nemours & Co.*, 117 F.R.D. 535, 538-39 (D.Del.1987).

The court notes that there is very little likelihood of injury to the attorney-client relationship under the circumstances of this case. First, the Magistrate ordered *in camera* review of the documents allegedly subject to waiver. This gives added protection to GE's attorney-client relationship because defendants will not be given access to the communications unless the Magistrate's review indicates that the subject documents actually bear upon GE's state of mind. Second, GE was not compelled to rebut evidence of fraudulent intent unless defendants made a *prima facie* showing of all three elements of common law fraud. Defendants had to do more than merely accuse GE of fraud. Under these circumstances the benefit gained for the correct disposal of the litigation outweighs whatever slight injury might be done to GE's attorney-client relationship.

III. *CONCLUSION*

Having conducted a *de novo* review of the record and of GE's objections, the Court concludes that defendants have made a sufficient showing under *United States v. Zolin* to justify *in camera* inspection of those privileged documents (identified at D.I. 109A Exhibit B) generated between November 13, 1986 and March 18, 1987. Accordingly, defendants' first motion to compel production of documents (D.I. 108) will be recommitted to the Magistrate to conduct an *in camera* review of the aforementioned documents, and to "hear and determine" the matter pursuant to 28 U.S.C. § 636(b)(1)(A).

***10** The Court also concludes that GE has effected a limited waiver of its attorney-client privilege. The Court adopts in its entirety the Magistrate's "recommendation" that Plaintiff produce for *in camera* inspection those documents: (a) as to subject matter, communications tending to show plaintiffs' knowledge regarding high-PET blends and their moldability under any conditions contemplated by the GE patent, and (b) as to time, from November 13, 1986, when the Examiner rejected plaintiff's claims, to March 18, 1987, when the Examiner allowed plaintiff's amended claims.

> FN1. A reasonable interpretation of the Magistrate's Order is that *in camera* review will screen out privileged communications that were not made in furtherance of a crime or fraud. GE agrees with this interpretation: "[T]he ordered *in*

camera inspection provides a necessary and desirable, antecedent, subject-matter screening by the Magistrate...." Letter from David A. Anderson to Hon. Jane R. Roth, dated Feb. 4, 1990.

FN2. The Court does not wish to imply that the Magistrate incorrectly applied the *Union Carbide* factors. Nor does the Court hold that *in camera* review is always the appropriate response to a claim of common law fraud. Indeed, *Zolin* teaches otherwise. *See Zolin*, 109 S.Ct. at 2631.

FN3. GE takes issue with this interpretation of the Examiner's request but offers no plausible alternative. GE seems to be arguing that the Examiner requested evidence that blends are different from copolymers *because they are different.* Such an assertion cannot be taken seriously. GE realized as much when it submitted the ABC experiment, which focused on the *moldability* of the blends and copolymers.

Not Reported in F.Supp., 1990 WL 154218 (D.Del.), 15 U.S.P.Q.2d 1673

Motions, Pleadings and Filings (Back to top)

• 1:87CV00458 (Docket) (Aug. 24, 1987)

END OF DOCUMENT

EXHIBIT F

Westlaw.
Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2005 WL 588341 (N.D.Cal.)
(Cite as: 2005 WL 588341 (N.D.Cal.))

H

Motions, Pleadings and Filings

Only the Westlaw citation is currently available.

United States District Court,
N.D. California.
ICU MEDICAL, INC., Plaintiff,
v.
B.BRAUN MEDICAL INC., Defendants.
No. C 01-3202 CRB.

March 14, 2005.

Christopher B. Hockett, Bingham McCutchen LLP, San Francisco, CA, Mary T. Huser, Thomas E. Kuhnle, Adrienne L. Taclas, Mary A. Fuller, Susan Vastano Vaughan, Bingham McCutchen LLP, East Palo Alto, CA, S. Christian Platt, Paul, Hastings, Janofsky & Walker LLP, San Diego, CA, for Plaintiff.

Tony L. Richardson, Kirkland & Ellis, Los Angeles, CA, Daniel F. Attridge, Edward C. Donovan, Gregory Corbett, John Thomas Battaglia, Justin P.D. Wilcox, Kirkland & Ellis LLP, Washington, DC, for Defendants.

ORDER RE: MOTIONS FOR SUMMARY JUDGMENT AND SCHEDULING TRIAL

BREYER, J.

*1 Plaintiff and Counterclaim Defendant ICU Medical, Inc. ("ICU") brought this suit against Defendant and Counterclaimant B.Braun Medical, Inc. ("Braun") for infringement of U.S. Patent No. 5,928,204 ("the '204 patent") and U.S. Patent No. 6,669,673 ("the '673 patent") by manufacturing and selling a specialized needleless medical connector. The patents relate to a medical valve for use in controlling the flow of fluid between two medical implements. The alleged infringing device is Braun's Ultrasite valve.

ICU and Braun cross-move for summary judgment on the issue of whether the Ultrasite valve [FN1] infringes the '673 patent. Braun also seeks summary judgment of non-infringement of both the '673 and '204 patents by the Ultrasite valve with modified piston. Finally, ICU moves for summary judgment that the '673 patent is not unenforceable due to inequitable conduct on the part of the patentee.

FN1. In late 2004, Braun made a modification to the Ultrasite valve by changing the molds used in manufacturing the piston component to remove an alleged "taper" in the piston skirt. The modified valve will be referred to in this Order as the Ultrasite valve with modified piston. Otherwise, the term "Ultrasite valve" will refer to both the unmodified Ultrasite valve and the Ultrasite valve with modified piston.

Having carefully considered the parties' papers, and with the benefit of oral argument on February 11, 2005, the Court hereby resolves the motions as follows:

1. ICU's motion for summary judgment that Braun's Ultrasite valve infringes the '673 patent is GRANTED in part as to claims 1-2 and 5-6, and DENIED in part as to claim 3.
2. Braun's motion for summary judgment that the Ultrasite valve does not infringe the '673 patent is DENIED in part as to claims 1-2 and 4-6, and GRANTED in part as to claim 3.
3. Braun's motion for summary judgment that the Ultrasite valve with modified piston does not infringe the '673 and '204 patents is GRANTED.
4. ICU's motion for summary judgment of no inequitable conduct is DENIED.

BACKGROUND

The administration of medication in hospital and medical settings routinely involves the use of connectors and adaptors for facilitating the movement of fluids (e.g., drugs and intravenous solutions) between medical implements. Since the ready passage of fluids through the connectors and adaptors is often critical to patient survival, it is important that they operate reliably and repeatedly. Both Braun and ICU are providers of needleless medical connectors.

Braun's Ultrasite valve is a needle-free, capless, swabbable valve. It contains a piston made of flexible material. When the piston is in its uncompressed state, it seals against the housing of the valve preventing fluid flow through the valve. In this state, the wall of the piston is relatively flat. When a

syringe or other appropriate medical device is connected to the valve, the piston is compressed causing the piston wall to buckle. The compressed piston no longer completely seals against the valve housing because the portion of the piston that seals against the housing is moved to a location where there are channels in the housing. When the piston is compressed, fluid can flow through the valve.

ICU is the assignee of two patents (the '673 and '204 patents) for a closed system, needleless valve device which automatically reseals after administering medication using a medical implement that directly connects with the system without the need of any intermediary needles, caps, or adaptors.

I. THE '673 PATENT

*2 Independent claim 1 reads:

> A medical valve for controlling the flow of fluid between a first medical implement and a second medical implement, said valve comprising:
> ....
> ... a flexible element positioned in said cavity movable between an uncompressed position in which a portion of the flexible element bears against the wall structure near said opening and obstructs fluid flow through said valve and a compressed position in which fluid flow is permitted through said valve, said flexible element comprising a wall with an inner surface and an outer surface, the wall flexing to accommodate axial compression of said flexible element, said flexible element comprising an end fitting against a ring shaped support to assist in securing said flexible element in said cavity, said flexible element in said uncompressed position comprising a first external diameter near said opening, a second external diameter in said main portion, said second diameter being smaller than said first diameter and said third diameter, and at least a portion of the outer surface of the wall of the flexible element between the second diameter and the third diameter being tapered.

U.S. Patent No. 6,669,673 (issued Dec. 30, 2003). Claims 2-6 are dependent claims from claim 1.

The Court issued its claim construction order regarding the '673 patent on November 8, 2004 (the "Markman Order"). In its Markman Order, the Court determined that the term "flexible element" should be defined as "a portion of the valve that is capable of being bent, usually without breaking." Markman Order at 7. The flexible element must be moveable from an uncompressed position, in which the valve is closed, to a compressed position, in which "it is under axial compression from a medical implement" and "the valve is in an open state and fluid is allowed to move through it." *Id.* at 9, 7. When the flexible element is in an uncompressed position, it must "bear against the wall structure" and "obstruct[ ] fluid flow" through the valve. '673 Patent Claim 1.

II. THE '204 PATENT

Independent claim 1 reads:

> A seal for use in selectively opening and closing a fluid pathway through a medical connector comprising a resilient seal element having a wall having a top end and a bottom end, said wall including at least two generally arcuate segments each having an outwardly extending portion, said segments intersecting one another and defining at least one space between where said segments intersect and a line tangential to the outwardly extending portions of both segments, and at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element.

U.S. Patent No. 5,928,204 (issued July 27, 1999). Claims 2-5 are dependent claims from claim 1.

DISCUSSION

ICU and Braun cross-move for summary judgment on the issue of whether Braun's Ultrasite valve infringes claims 1-3 and 5-6 of the '673 patent. Braun also seeks summary judgment of non-infringement by the Ultrasite valve with modified piston with regard to claims 1-6 of the '673 patent and claims 1-5 of the '204 patent. Finally, ICU moves for summary judgment that the '673 patent is not unenforceable due to inequitable conduct on the part of the patentee.

I. STANDARD OF REVIEW FOR SUMMARY JUDGMENT

*3 Summary judgment is appropriate when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). An issue is "genuine" only if there is sufficient evidence for a reasonable fact finder to find for the non-moving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A fact is "material" if the fact may affect the outcome of the case. *See id.* at 248. "In considering a motion for summary judgment, the court may not weigh the evidence or make credibility

determinations, and is required to draw all inferences in a light most favorable to the non-moving party." *Freeman v. Arpaio*, 125 F.3d 732, 735 (9th Cir.1997). A principal purpose of the summary judgment procedure is to identify and dispose of factually unsupported claims. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

The party moving for summary judgment bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *See id.* at 323. Where the moving party will have the burden of proof on an issue at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *See id.* Once the moving party meets this initial burden, the non-moving party must go beyond the pleadings and by its own evidence "set forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e). The non-moving party must "identify with reasonable particularity the evidence that precludes summary judgment." *Keenan v. Allan*, 91 F.3d 1275, 1279 (9th Cir.1996) (quoting *Richards v. Combined Ins. Co.*, 55 F.3d 247, 251 (7th Cir.1995), and noting that it is not a district court's task "to scour the record in search of a genuine issue of triable fact"). If the non-moving party fails to make this showing, the moving party is entitled to judgment as a matter of law. *See Celotex*, 477 U.S. at 323.

II. INFRINGEMENT OF THE '673 PATENT

A patent infringement analysis involves two steps: claim construction and then applying the construed claim to the accused device. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995). The first step, construing the claims to determine their meaning and scope, has been held to be purely a matter of law. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed.Cir.1998). The second step, application of the claim to the accused device, is a fact-specific inquiry. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed.Cir.1998) ("[I]nfringement, whether literal or under the doctrine of equivalents, is a question of fact."). If each limitation of the patent claim is found in the accused device, either literally or as a substantial equivalent, the accused device infringes that claim. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997).

***4** Summary judgment is appropriate in infringement suits when, drawing all reasonable inferences in favor of the non-moving party, there is no genuine issue of material fact. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed.Cir.1999). Because the relevant aspects of the accused device's structure and operation are undisputed in this case, the question of infringement collapses to one of claim construction and is particularly amenable to summary judgment. *Id.*

A. Literal Infringement

To establish literal infringement, the accused device must "contain each limitation of the claim exactly." *Litton Sys., Inc. v. Honeywell Inc.*, 140 F.3d 1449, 1454 (Fed.Cir.1998). The Court will proceed to compare the accused Ultrasite valve against all the claims and each of their limitations.

1. Claim 1 of the '673 patent

Claim 1 is the only independent claim of the '673 patent. It claims a medical valve for *controlling the flow of fluid* comprising a *flexible element* that: (1) *obstructs fluid flow* through the valve, (2) comprises *a wall flexing to accommodate axial compression* by a medical implement, (3) comprises *an end fitting against a ring shaped support*, and (4) is *tapered*. ICU asserts that Braun's Ultrasite valve satisfies each of these elements.

a. "Controlling the flow of fluid"

The Ultrasite valve plainly controls the flow of fluid from one medical implement to another. Braun's argument that its Ultrasite valve does not control fluid flow between two medical implements fails even under its own offered definition in which "control" means "to exercise restraint *or* direction over." Braun's Opposition Memorandum at 19 (quoting Random House Dictionary 442 (2d ed.1983)) (emphasis added). Removing the implement inserted into the top of the Ultrasite valve restrains the flow of fluid as the piston moves toward its uncompressed position. Inserting a medical implement opens the valve, allowing fluid to flow between that implement and another implement connected to the other end of the valve. When the Ultrasite valve connects two medical implements, it controls the flow of fluid by restraining the fluid within the valve and directing the flow from one implement to the other.

The term "control" should not be read so narrowly as to require the regulation of any "maximum" or

"minimum" fluid flow. The preferred embodiments in the '673 patent work in a similar way (as does the Ultrasite valve) to control the flow of fluid between two medical implements: inserting a syringe or other medical implement opens the valve by exposing passageways that allow fluid to flow from one implement to the other. The '673 patent does not recite a medical valve that independently starts, shuts off, slows-down, or speeds-up the flow of fluids. To accept Braun's argument would exclude the elected embodiments of the '673 prosecution, and produce a highly disfavored result for which Braun provides insufficient support. *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*, 362 F.3d 1367, 1381 (Fed.Cir.2004) (vacating summary judgment of non-infringement where accused infringer's claim interpretation would have excluded patent's preferred embodiment; such an interpretation is "rarely, if ever, correct.").

b. "Flexible element" that "obstructs fluid flow"

*5 Braun's Ultrasite valve also comprises a flexible element that obstructs fluid flow through the valve. In its claim construction, the Court construed the disputed claim language as follows. The term "flexible element" means "a portion of the valve that is capable of being bent, usually without breaking." Markman Order at 7. ICU does not assert that the entire piston assembly (including the piston component, rigid plug, and spring) constitutes the flexible element. Rather, ICU contends that only the piston component, or piston, infringes the "flexible element" limitation of claim 1. [FN2] ICU's Reply Memorandum at 4-5.

> FN2. For the purposes of this Order, the term "piston" refers to the piston component as opposed to the entire piston assembly.

The piston is clearly a flexible element under the claim language. It is made in a single molding of an elastomeric material, which allows it to flex or bend without breaking. The piston bends at several points during operation of the valve. In the uncompressed position, the lip of the piston flexes in response to radial pressure as it is squeezed into the neck of the housing. The shoulder of the piston flexes when it is pressed against the housing shoulder. The neck of the piston also flexes during insertion of the rigid plug and spring at assembly. The piston skirt flexes in response to axial pressure when it is moved into a compressed position by a medical implement.

Braun contends that the elastomeric piston is not "flexible" inside the valve because the rigid plug inserted into the neck of the piston is not flexible. The Court's construction, however, does not require that the flexible element must be bent, only that it is *capable* of being bent. Insertion of the rigid plug does not change the fact that the piston is still capable of being bent in response to pressure (e.g., radially from the rigid plug or housing wall, and axially from the medical implement), which is all the claim requires. Indeed, insertion of the rigid plug causes the piston neck to flex in response to radial pressure, and insertion of a medical implement causes the piston skirt to flex in response to axial pressure when it is moved into a compressed position.

Braun further contends that ICU's position is inconsistent with its earlier claim that the Ultrasite valve satisfies a "rigid sealing element" limitation in U.S. Patent No. 6,245,048 (the '048 patent). Claim 1 of the '048 patent recites "a rigid sealing element ... movable between a first position in which said seal prevents fluid flow and a second position in which fluid flow is permitted...." Braun's argument fails because ICU is not contending that the same features of the valve are both a "rigid sealing element" and a "flexible element." Rather, ICU refers to the stiffened lip and neck portion of the combined piston assembly as the "rigid sealing element," but only the piston component as the "flexible element." Although the Ultrasite piston assembly as a whole is rigid, the piston component remains flexible. It does not follow that a stiffened piston assembly cannot comprise a "flexible" piston which is capable of bending in response to pressure.

*6 The piston also obstructs fluid flow through the valve. In an uncompressed position, the lip of the piston bears against the housing wall and the rigid plug to create a seal that obstructs fluid from entering the valve. The piston shoulder also bears against the internal housing wall and prevents fluid from flowing through the valve. Insertion of a medical implement pushes down on the rigid plug, which moves the piston from an uncompressed position to a compressed position in which fluid is allowed to flow through passageways in the valve.

Braun's argument that the rigid plug, not the piston, obstructs fluid flow through the valve is not supported by the evidence. In the Ultrasite valve, the fluid path is around the outside of the piston assembly, not through it. Even without the rigid plug, the piston bears against the housing wall near the valve opening and at the piston shoulder, blocking the passageways that allow fluid to flow through the

valve. Although the piston component is hollow, a fluid barrier exists at the base where the piston is compressed between the luer nut and the housing wall. So even without a rigid plug, the piston obstructs fluid flow.

Moreover, Braun's contention that the piston or flexible element alone must obstruct fluid flow through the Ultrasite valve is not what the claim requires. Claim 1 is a "comprising" claim for "a medical valve ... comprising ... a flexible element ... [that] obstructs fluid flow...." A claim that incorporates the term "comprising" is "generally understood to signify that the claims do not exclude the presence in the accused apparatus ... of factors in addition to those explicitly recited." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 811-12 (Fed.Cir.1999) (reversing summary judgment of non-infringement where accused device included features in addition to elements claimed in a "comprising" claim); *see also Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed.Cir.1991) (a claim "which uses the term 'comprising,' is an 'open' claim which will read on devices which add additional elements"). "The signal 'comprising' implements the general rule that absent some special circumstance or estoppel which excludes the additional factor, infringement is not avoided by the presence of elements ... in addition to those specifically recited in the claim." *Vivid Techs.*, 200 F.3d at 811.

Here, Braun cannot escape infringement by pointing to other elements in the Ultrasite valve such as the rigid plug that also obstruct fluid flow. There are no special circumstances and Braun has not pointed to anything in the '673 prosecution history that would allow it to evade the general rule that an accused infringer cannot escape infringement by pointing to elements in his device that are in addition to those elements in the claimed invention. *See id.* Braun's Ultrasite valve infringes despite the fact that the piston component is not the only element obstructing fluid flow through the valve.

c. "A wall flexing to accommodate axial compression"

*7 The Ultrasite valve also comprises a wall that flexes to accommodate axial compression. The claim recites "a flexible element ... comprising a wall ... flexing to accommodate axial compression." Braun's argument that there can be only one wall that flexes (its entirety) in the flexible element in response to axial compression is not what the claim requires. The claim describes a flexible element that comprises or includes "a wall" that flexes in response to axial compression, but may also include other parts that do not flex in response to axial pressure. [FN3] The claim should not be read to require that the entire piston must flex to accommodate axial compression. *See Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed.Cir.1988) ("Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims.").

> FN3. As ICU correctly notes, the use of the indefinite article "a" in an open-ended, "comprising" claim does not limit that claim to the singular. *KJC Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed.Cir.2000) ("This court has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.' ").

Here, the piston component is the flexible element. Inserting a syringe or other medical implement moves the piston into a compressed position and causes the piston skirt to flex in response to axial pressure. Accordingly, the piston skirt is *a wall* that flexes to accommodate axial compression of the piston, and satisfies the claim limitation.

d. "An end fitting against a ring shaped support"

Claim 1 of the '673 patent also requires that the flexible element has an "end fitting against a ring shaped support." In its claim construction, the Court found the term "ring shaped support" to be unambiguous. Markman Order at 11. In the Ultrasite valve, the piston component sits on top of the Luer nut, which makes up the bottom part of the body of the housing. Braun contends that the Luer nut presents nothing more than "a flat surface on which the piston assembly sits" and cannot constitute a "ring shaped support." Braun's Opposition Memorandum at 20. The top surface of the Luer nut, however, is not flat. The "annular sealing ring" on the face of the Luer nut includes a concentric series of ring-shaped ridges. The piston plainly fits against a ring-shaped support, which helps to secure the piston in the housing body, and satisfies the claim limitation.

e. "At least a portion ... of the wall ... being tapered"

The final limitation of claim 1 requires that a portion of the wall of the flexible element be "tapered" between the second and third diameters. The parties

agree that "tapered" means "to make gradually diminished in width toward one end." Braun's Opposition Memorandum at 21. ICU asserts that the skirt of the piston component in the Ultrasite valve satisfies this limitation.

Braun does not refute the assertion that its unmodified Ultrasite valve meets the "taper" limitation. Indeed, the valve contains a slight taper along the skirt of the piston component. Braun states that the taper is a draft mold, or a well-known non-functional by-product of the manufacturing process. Nevertheless, the piston skirt gradually diminishes in width towards one end of the Ultrasite valve structure as the claim requires.

***8** Braun contends, however, that to the extent a slight mold draft on the unmodified valve could be considered a taper, Braun has now removed it from the Ultrasite product. The piston component of the newly modified valve is no longer tapered. Instead, the piston skirt consists of straight walls. The question of whether the new, modified Ultrasite valve infringes the '673 patent is considered further below.

As to the unmodified Ultrasite valve, Braun has failed to raise any material issue of fact to rebut ICU's showing that it contains each limitation of claim 1 of the '673 patent. Consequently, the Court finds that the accused unmodified Ultrasite valve literally infringes claim 1 of the '673 patent.

2. Claim 2 of the '673 patent

Claim 2 of the '673 patent incorporates all the limitations in claim 1 and adds that an end of the flexible element in its uncompressed position near the opening must be "substantially flat." The lip of the Ultrasite valve's piston component is substantially flat. Braun contends, however, that "the end of the piston that is closest to the opening is substantially open, not flat." Braun's Opposition Memorandum at 23. But claim 2 does not require the end of the piston component to be both flat and disc-shaped as opposed to ring-shaped. Therefore, the Court finds that the accused unmodified Ultrasite valve literally infringes claim 2 of the '673 patent.

3. Claim 3 of the '673 patent

Claim 3 of the '673 patent incorporates all the limitations in claim 1 and adds that an end of the flexible element in its uncompressed position must be "substantially flush with the opening of said cavity of said body." ICU contends that "substantially" is a modifier implying "approximately" rather than "perfect." ICU's Reply Memorandum at 12; *see also* *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1368-69 (Fed.Cir.2004) (noting that the term "substantial" is a modifier implying "approximate," rather than "perfect"). But the Ultrasite valve's piston component is not even "approximately" flush with valve opening. Instead, it is recessed in the cavity of the valve near the opening. The lip of the piston component sits beneath the rigid plug, which in turn sits below the top surface of the valve opening. Therefore, the Court finds that the Ultrasite valve does not literally infringe claim 3 of the ' 673 patent.

4. Claim 5 of the '673 patent

Claim 5 of the '673 patent incorporates all the limitations in claim 1 and adds that the flexible element must comprise "a single molding." The parties agree that "comprises a single molding" means "formed from a single mold." Markman Order at 13. The Ultrasite piston component is molded as a single piece, which satisfies the claim limitation. Therefore, the Court finds that the Ultrasite valve literally infringes claim 5 of the '673 patent.

5. Claim 6 of the '673 patent

Claim 6 of the '673 patent incorporates all the limitations in claim 1 and adds that the valve must further comprise of "a rigid member positioned within the flexible element and to assist in maintaining the flexible element along an axial centerline when the flexible element moves between the uncompressed position and the compressed position." The rigid plug in the Ultrasite valve satisfies this claim limitation. The rigid plug is made of a hard plastic, sits within the piston component, and prevents the piston assembly from bending when it is axially compressed. Braun contends that ICU undermines its infringement arguments regarding claim 1 because the piston component cannot be a "flexible element" if the rigid plug satisfies the "rigid member" limitation. This argument has already been rejected by the Court in its discussion of infringement of claim 1. Therefore, the Court finds that the unmodified Ultrasite valve literally infringes claim 6 of the '673 patent.

III. INFRINGEMENT OF THE '673 AND '204 PATENTS BY THE ULTRASITE VALVE WITH MODIFIED PISTON

***9** The '673 patent requires, among other things, a medical valve comprising a "flexible element" having

at least three "external diameters," with "at least a portion of the outer surface of the wall of the flexible element between the second diameter and the third diameter being tapered." Similarly, the '204 patent requires a "resilient seal element" having "at least two generally arcuate segments" with "at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element." The claim limitation requiring different-sized maximum diameters was added during prosecution of the '204 patent, and ICU has asserted that this created a "taper" limitation.

Braun does not refute the assertion that its unmodified Ultrasite valve contains a slight taper in the skirt of the piston component. Instead, it contends that the newly modified Ultrasite piston is straight-walled and cannot satisfy the "taper" limitation. In September and October of 2004, Braun modified the molds used to make the piston component to eliminate any mold draft. As a result, the modified piston component used in Ultrasite valves being manufactured today has straight walls. Braun has removed the alleged "taper" from the Ultrasite product, and now moves for summary judgment that the Ultrasite valve with modified piston does not infringe claims 1-6 of the '673 patent and claims 1-5 of the '204 patent.

A. Subject Matter Jurisdiction

Contrary to ICU's assertions, the Court has jurisdiction to decide Braun's summary judgment motion of non-infringement of the '673 and '204 patents by the Ultrasite valve with modified piston.

Under the Declaratory Judgment Act, a federal court may exercise jurisdiction over a matter only in "a case of actual controversy." 28 U.S.C. § 2201(a). The courts are forbidden from rendering advisory opinions. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed.Cir.1988). The test for determining whether an "actual controversy" exists involving patents is objective and two-pronged. First, an alleged infringer must have a reasonable apprehension that the patent holder will initiate suit if the party continues the allegedly infringing activity. Second, the alleged infringer must have either produced the device or have prepared to produce that device. *Id.* at 735-36.

Although subject matter jurisdiction is decided at the time of filing, once it has been established, a court may adjudicate all those claims and related defenses brought by the parties throughout the litigation as long as an "actual controversy" continues to exist. *See Preiser v. Newkirk*, 422 U.S. 395, 401, 95 S.Ct. 2330, 45 L.Ed.2d 272 (1975) ("The rule in federal cases is that an actual controversy must be extant at all stages of review, not merely at the time the complaint was filed"). For this reason, plaintiffs do not need to file a new action on the same patent for each modification made to an accused product during the course of litigation. Notably, the modified Ultrasite valve is not a new valve but a modification to one component of the same valve.

***10** The Court has jurisdiction over the newly modified Braun Ultrasite valve. In its Complaint, ICU generically alleges that Braun is infringing the '673 and '204 patents "by making, using, offering for sale, and selling within the United States Braun's *Ultrasite needleless medical connectors.*" First Amended Complaint at ¶ 7 (emphasis added). The newly-modified Ultrasite valve is essentially the same product ICU has accused of infringement in its Complaint, except the elastomeric piston component no longer has the non-functional mold draft that ICU alleges satisfies the "taper" limitation. In addition, ICU identifies in its Infringement Disclosures Braun's Ultrasite valve product family as "accused instrumentalities," including any future ones it may find in discovery: "ICU anticipates identifying additional infringing B.Braun Ultrasite Needle-Free Valve products after conducting discovery in this matter." [FN4] ICU's 3/31/04 Amended Initial Disclosure of Asserted Claims Under Patent L.R. 3-1.

> FN4. Further, ICU seeks damages on sales during the litigation and an injunction against future sales. These remedies cannot be decided without first determining whether the Ultrasite valves with modified piston infringe the '673 and '204 patents, because Braun does not make any more Ultrasite valves with unmodified pistons for sale in the United States.

Moreover, jurisdiction exists under Braun's declaratory counterclaim that its generic "Ultrasite needleless medical connectors" do not infringe the '673 patent. Braun's 3/5/04 Answer and Counterclaims at 12. An actual controversy existed at the time of filing because the parties were already in litigation over the Ultrasite valve product family, and Braun was making and selling the accused devices. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993) ("If ... a party has actually been charged with infringement of the patent, there is, *necessarily*, a

case or controversy adequate to support jurisdiction of a complaint, or a counterclaim under the Act."). Braun's decision to modify the molds used to manufacture the piston component and remove the alleged "taper" in the piston skirt did not divest the court of its jurisdiction over Ultrasite needleless medical connectors.

Jurisdiction over the newly modified Ultrasite valve also exists because Braun had a reasonable apprehension that ICU would initiate suit because it was already litigating the action and ICU had not stipulated to non-infringement by the Ultrasite valve with modified piston. The evidence also shows that all the molds used to make pistons for Ultrasite products for sale in the United States were changed by October 2004, and valves with modified pistons were being commercially sold and used by customers. Even if Braun had only switched the molds but was not yet selling the modified valve to customers, an actual controversy still exists because Braun had prepared to produce the Ultrasite valve with modified piston. *See Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575 (Fed.Cir.1986) ("[T]he statutory requirement is satisfied when ... the plaintiff has 'actually produced the accused device' *or* has 'prepared to produce such a device.' ") (emphasis added).

It is not necessary for ICU to make any allegations regarding the redesigned product in order for the Court to have jurisdiction over the Ultrasite valve with modified piston. Jurisdiction existed when ICU filed the infringement action against generic Ultrasite valves, and continues to the present day. There is no heightened pleading standard for identifying specific modifications for accused products in infringement actions. *See* Fed.R.Civ.P. 9 (specifying the claims and defenses that require pleading with particularity).

***11** ICU's reliance on *Laitram Corp. v. Cambridge Wire Cloth Co.*, 919 F.2d 1579 (Fed.Cir.1990), is misplaced. Although the court in *Laitram* vacated summary judgment of non-infringement for lack of jurisdiction because the motion addressed products never accused of infringement, the facts are distinguishable from this case. There, the Federal Circuit was concerned with the *complete absence* of an accused product. *Laitram*, 919 F.2d at 1580 ("[T]he present record contains no evidence that any product accused of infringement had been made, used, or sold when the complaint was filed."). The only products before the district court when it granted summary judgment were the non-accused "possible constructions" of the product. *Id.* at 1581. Consequently, the Federal Circuit held that there was no true case or controversy. *Id.* ("In its motion, [plaintiff] was effectively and improperly saying to the district court, 'if we make and sell any of these four "possible constructions" please advise that we won't infringe.' Federal Courts do not sit, however, to decide hypotheticals or to issue advisory opinions."). In contrast, the accused Braun Ultrasite valves with modified piston are being made, used, and sold. Moreover, the Ultrasite valve with modified piston was not merely a "possible construction" of the product. By the end of 2004, Braun had modified the molds used to produce the piston component for all the Ultrasite valves manufactured and sold in the United States.

ICU also relies on *Field Container Co., L.P. v. Somerville Packaging Corp.*, 842 F.Supp. 338 (N.D.Ill.1994). The facts in *Field Container* are also inapposite to this case. There, the court found that the plaintiff in a declaratory judgment action failed to satisfy the burden of demonstrating an actual controversy. *Id.* at 342-43. A letter threatening legal action sent to the plaintiff could not establish a reasonable apprehension of suit because it referenced an older version of the product that was "significantly different" from the version then being produced by the plaintiff. *Id.* at 342 ("We are therefore unwilling to apply the transitive property and convert any 'reasonable apprehension of suit' with respect to Version 1 to a 'reasonable apprehension of suit' with respect to Version 2."). Consequently, the court had no jurisdiction over the product at issue. In contrast, the difference between Braun's two Ultrasite valves is not substantial enough to bar a reasonable apprehension of suit with respect to the modified Ultrasite valve when ICU initiated its litigation against Braun's unmodified valve. Indeed, the two versions of the valve are almost identical. The mold draft on the piston component was a by-product of the manufacturing process, not a functional attribute of the product. Its removal did not alter the function or operation of the valve. Thus, it was reasonable for Braun to fear being sued for infringement if it manufactured the modified valve, particularly in light of ICU's refusal to stipulate to non-infringement by the Ultrasite valve with modified piston. Braun satisfied its burden to demonstrate that an actual controversy exists, and the Court has jurisdiction to consider whether the Ultrasite valve with modified piston infringes the '673 and '204 patents.

B. Non-Infringement

*12 The Court now turns to the merits of Braun's summary judgment motion with respect to the Ultrasite valve with modified piston. Both the '673 and '204 patents recite a medical valve containing a tapered structure. The parties agree that "tapered" means "to make gradually diminished in width toward one end." Braun's Opposition Memorandum at 21.

ICU asserts that the skirt of the piston component in Braun's Ultrasite valve satisfies this limitation. As to the Ultrasite valve with modified piston, Braun has now removed the alleged "taper" from the product. The piston skirt no longer gradually diminishes in width towards one end. Design drawings of the modified piston component show that the piston is no longer tapered. The piston skirt now consists of straight walls. Notably, even ICU does not contend that the modified Ultrasite product infringes (either literally or by virtue of the doctrine of equivalents) the '673 and '204 patents.

Thus, there is no genuine dispute that the modified Ultrasite valve does not infringe the '673 and '204 patents, and the Court grants Braun's motion for summary judgment of non-infringement by the Ultrasite valve with modified piston.

IV. INEQUITABLE CONDUCT

Braun has alleged in its pleadings that ICU's '673 patent is unenforceable because of the inequitable conduct of ICU during the prosecution of the '673 patent before the Patent and Trademark Office ("PTO").

Specifically, Braun argues that ICU committed inequitable conduct by failing to disclose the existence of this ongoing litigation and relevant litigation materials regarding infringement by the Ultrasite valve to the '673 patent examiner, while simultaneously prosecuting a new patent application with a petition alleging infringement by the same Ultrasite valve.

The '673 patent application was filed as a continuation of an abandoned application originally filed in December 1991. The inventor, Dr. George Lopez, [FN5] successfully petitioned for an expedited examination of the application based on the alleged infringement of the new invention by Braun's Ultrasite valve. The petition did not disclose that the assignee of the '673 patent, ICU, had already been in litigation with Braun over the same Ultrasite valve for over a year. It also failed to inform the PTO that ICU alleged in the ongoing litigation that the same Ultrasite valve infringed the '204 patent-- a patent that shares the same specification as the '673 patent.

> FN5. Dr. Lopez is also the inventor of the '204 patent and the Chief Executive Officer of plaintiff ICU Medical, Inc.

ICU, however, contends that there is no evidence of inequitable conduct on its part as to the prosecution of the '673 patent. ICU points out that the PTO was notified by the Clerk of the United States District Court for the Northern District of California as to the pending litigation involving the '048 and '673 patents pursuant to 35 U.S.C. § 290. Moreover, ICU disclosed all relevant prior art, including every prior art patent raised during the course of litigation, [FN6] to the PTO during the '673 prosecution in accordance with the applicable regulations. ICU argues that there is no evidence of any intent on its part to deceive or mislead the PTO.

> FN6. The list of relevant prior art references raised during the course of litigation and disclosed by ICU to the PTO include: Armao (U.S. Patent No. 3,134,380), Adams (U.S. Patent No. 2,847,995), Vailancourt (U.S. Patent No. 4,512,766), DeFrank (U.S. Patent No. 5,242,432), Cambio (U.S. Patent No. 4,201,208), and Lopez (U.S. Patent No. 4,782,841).

*13 The Court finds that the existence of this ongoing litigation was material to the '673 patent prosecution, and that ICU failed to disclose this information to the '673 patent examiner. There is also sufficient evidence to raise a genuine issue of triable fact as to whether ICU failed to disclose this ongoing litigation with the intent to mislead or deceive the PTO. Consequently, summary judgment in favor of ICU with respect to Braun's affirmative defense of inequitable conduct as to the '673 patent is not appropriate.

A. Applicable Law

A patent applicant's duty to disclose material information to the PTO arises under the general duty of candor, good faith, and honesty as set forth in 37 C.F.R. § 1.56(a), which states, in part:

> Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material

to patentability as defined in this section.
37 C.F.R. § 1.56(a).

The Manual of Patent Examining Procedure ("MPEP") further provides:

> Where the *subject matter* for which a patent is being sought is or has been involved in litigation, *the existence of such litigation and any other material information arising therefrom* must be brought to the attention of the Patent and Trademark Office; such as, for example, evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of 'fraud,' 'inequitable conduct,' or violation of duty of disclosure. Such information might arise during litigation in, for example, pleadings, admissions, discovery including interrogatories, deposition, and other documents, and testimony.

MPEP § 2001.06(c) (emphasis added). Although MPEP § 2001.6(c) is not binding law, it sheds light on the PTO's official interpretation of 37 C.F.R. § 1.56(a) regarding the materiality of related litigation.

A patentee commits inequitable conduct if, "during prosecution of the application, he makes an affirmative representation of material fact, fails to disclose material information, or submits false material information, and does so with intent to deceive." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1358 (Fed.Cir.2003) (citation omitted). To find inequitable conduct, there must be clear and convincing evidence that both the materiality and intent prongs of the test are satisfied. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1233 (Fed.Cir.2003).

1. Sufficiency of § 290 Notice

ICU contends that the ongoing litigation relating to infringement by the Ultrasite valve was properly disclosed and brought to the attention of the PTO when the Clerk gave notice of this litigation pursuant to 35 U.S.C. § 290. [FN7]

> FN7. 35 U.S.C. § 290 provides:
> The clerks of the courts of the United States, within one month after the filing of an action under this title shall give notice thereof in writing to the Director, setting forth so far as known the names and addresses of the parties, name of the inventor, and the designating number of the patent upon which the action has been brought.... The Director shall, on receipt of such notices, enter the same in the file of such patent.

The duties imposed by 37 C.F.R. § 1.56(a) and MPEP § 2001.06(c) cannot be supplanted by the general administrative notice required by Section 290. The patent applicant has an independent duty to disclose the existence of related patent infringement litigation to the PTO examiner. The duty of disclosure is particularly important in the context of patent prosecutions, which are conducted before an examiner in the absence of any represented adversary. In *ex parte* patent prosecutions, PTO examiners rely on the patent applicants to make full disclosure of material information of which they are aware in each case. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 147 (D.Mass.2001) ("[T]he duty of candor ultimately falls on the shoulders of the patent applicant...."). Moreover, the PTO has hundreds of examiners who handle hundreds of thousands of applications annually, and one examiner is unlikely to be aware of the status or assertions that an applicant makes to another examiner.

***14** Here, for example, although the Section 290 notice was sent to the PTO Director on the day the ongoing patent infringement action was filed, the PTO was directed under Section 290 to file the notice in the '204 and '048 patent file histories. Any Section 290 notice would not go to the examiner of the subsequent '673 patent application--a different, but related patent application. Indeed, the Section 290 notice appears nowhere in the '673 file history. As a result, the '673 patent examiner was unaware of this Court's claim constructions on similar language from the '204 and '048 patents. The '673 patent examiner was never told about Braun's invalidity contentions. The '673 patent examiner was never shown *any* of the pleadings or documents in this litigation. Consequently, ICU cannot rely on Section 290 to satisfy its duty to disclose the existence of related litigation to the '673 patent examiner.

In fact, the PTO advises that "the individuals covered by 37 C.F.R. 1.56 cannot assume that the examiner of a particular application is necessarily aware of other applications which are 'material to patentability' of the application in question, but must instead bring such other applications to the attention of the examiner." MPEP § 2001.6(b). [FN8] Likewise, an applicant cannot assume that an examiner, however diligent and well-informed, will be aware of Section 290 notices in other patents. To do so would effectively eviscerate the duty of disclosure regarding related litigation owed to each patent examiner.

> FN8. Furthermore, applicants should "continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. An incentive remains to submit the information to the Office because it will result in a strengthened patent and will avoid later questions of materiality and intent to deceive." *Critikon,* 120 F.3d at 1257.

2. Materiality

Information must be disclosed to the PTO when it is material to patentability. Materiality is not limited to prior art but includes "any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent. *Bristol-Myers,* 326 F.3d at 1234. According to the PTO, information is material to patentability if:

> It is not cumulative to information already of record [in the application], and
> (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
> (2) It refutes, or is inconsistent with, a position the applicant [has taken] in:
> (i) Opposing an argument of unpatentability relied on by the [PTO], or
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b).

In fact, related litigation is material *per se. See* MPEP § 2001.06(c) (stating that "the existence of such litigation *and any other* material arising therefrom" is material); *see also Daimlerchrysler AG v. Fueling Advanced Techs., Inc.*, 276 F. Supp 2d 1054, 1063 (S.D.Cal.2003). Failure to disclose related litigation may lead to a finding of inequitable conduct. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1255-59 (Fed.Cir.1997); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F.Supp.2d 508, 550-51 (D.N.J.1999) (denying patentee's preliminary-injunction motion because accused infringer had substantial defense of inequitable conduct based on patentee's failure to disclose materials from a related litigation to the examiner).

***15** The materiality of the '204 and '048 patent litigation which challenged both the validity and enforceability of the subject matter of the '673 application is obvious. Indeed, even ICU does not dispute that this ongoing litigation was material to the '673 patent prosecution. ICU Brief at 5-6. The '204 patent shared the same specification and disclosed the same subject matter as the '673 application. Braun also raised invalidity contentions against the patents-in-suit and alleged inequitable conduct against ICU in connection with its prosecution of the '048 patent, which may have been material to patentability of the '673 application. *See* MPEP § 2001.6(c) ("Examples of [ ]material information include ... allegations of 'fraud,' 'inequitable conduct,' and 'violation of duty of disclosure.' ").

3. Intent

As a general principle, the requirements of materiality and intent are inversely proportional. *See Critikon,* 120 F.3d at 1257. "A lesser quantum of intent is necessary when the omission or misrepresentation is highly material, and vice versa." *Diamlerchrysler,* 276 F.Supp.2d at 1065 (quoting *Amgen,* 314 F.3d at 1358). Nevertheless, the intent to deceive or mislead cannot be inferred solely from the materiality of the omission. *Amgen,* 314 F.3d at 1358. Proof of intent to mislead may be shown by circumstantial evidence. *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1189-90 (Fed.Cir.1993) (" '[S]moking gun' evidence is not required in order to establish an intent to deceive.... Rather, this element of inequitable conduct, must generally be inferred from the facts and circumstances surrounding the applicant's overall conduct.") (citation omitted).

A relatively high degree of intent may be demonstrated from the facts of this case. ICU was clearly aware that the subject matter of the pending litigation was material to the '673 patent prosecution. It knew that the claims of the '673 patent "read on" Braun's Ultrasite valve because it specifically alleged infringement by the Ultrasite valve in a Petition to Make Special to expedite examination of the '673 patent. Braun suggests that ICU's effort to obtain the '673 patent in time for use in this litigation provided a significant incentive for ICU to hide this litigation from the PTO examiner. [FN9]

> FN9. Indeed, disclosing the ongoing litigation may have forced ICU to address their various positions during litigation and consequently delayed the '673 patent prosecution by raising relevant invalidity defenses and material prior art. For example, the PTO examiner may have asked for more information regarding ICU's claim

> construction arguments that the '204 patent claims, which share the same specification as the '673 application, required a "taper" on the "resilient seal element" even if that term is never used. ICU relied on this "taper" limitation in opposing Braun's summary judgment motion for patent invalidity. Although the PTO examiner never had the opportunity to consider this information, ICU subsequently added an express "taper" limitation to the application claims of the '673 patent before it issued.

During the prosecution of the '673 application, ICU also objected to Braun's motion to compel production of pending ICU patent applications that were related to the '204 patent. ICU repeatedly told Magistrate Judge James that the applications were not "relevant," despite having already filed a Petition to Make Special alleging infringement by the same Ultrasite valve. This made it impossible for Braun to inform the '673 patent examiner of the pending litigation.

Put another way, ICU may have been trying to hide the pending litigation from the '673 patent examiner while simultaneously using the alleged infringement by the Ultrasite valve as a reason to expedite issuance of the '673 patent, which ICU could then use as a weapon in the ongoing litigation.

***16** ICU's reliance on *Haney v. Timesavers, Inc.*, 900 F.Supp. 1378, 1382 (D.Or.1995) (stating that "the court cannot infer an intent to deceive ... from the manner in which the information was conveyed to the Patent Office when the information was, in fact, conveyed.") is misplaced. In *Haney*, the district court found insufficient evidence to infer an intent to deceive and sustain an inequitable conduct claim. *Id.* Here, however, there is substantial evidence from which the Court could find that ICU had the intent to deceive the PTO regarding ongoing litigation surrounding the Ultrasite valve. ICU's failure to disclose the existence of this ongoing litigation regarding infringement by the Ultrasite valve to the '673 patent examiner, as well as the existence of the '673 application during discovery, while simultaneously prosecuting a new patent application with a petition alleging infringement by the same valve, raises a genuine issue of triable fact as to inequitable conduct.

CONCLUSION

For the reasons stated above, the Court hereby resolves the motions as follows:

1. ICU's motion for summary judgment that Braun's Ultrasite valve infringes the '673 patent is GRANTED in part as to claims 1-2 and 5-6, and DENIED in part as to claim 3.
2. Braun's motion for summary judgment that the Ultrasite valve does not infringe the '673 patent is DENIED in part as to claims 1-2 and 4-6, and GRANTED in part as to claim 3.
3. Braun's motion for summary judgment that the Ultrasite valve with modified piston does not infringe the '673 and '204 patents is GRANTED.
4. ICU's motion for summary judgment of no inequitable conduct is DENIED.

It is further ORDERED that trial on the issue of inequitable conduct shall begin on April 11, 2005 at 8:30 a.m. A pretrial conference shall be held on March 31, 2005 at 2:30 p.m.

IT IS SO ORDERED.

Not Reported in F.Supp.2d, 2005 WL 588341 (N.D.Cal.)

Motions, Pleadings and Filings (Back to top)

- 3:01cv03202 (Docket) (Aug. 21, 2001)

END OF DOCUMENT

EXHIBIT G

Westlaw.
1987 WL 16888
Not Reported in F.Supp., 1987 WL 16888 (E.D.Pa.), 9 Fed.R.Serv.3d 152
(Cite as: 1987 WL 16888 (E.D.Pa.))

H

United States District Court, E.D. Pennsylvania.
MANVILLE SALES CORP.
v.
PARAMOUNT SYSTEMS, INC.
Civ. A. No. 86-4157.

September 11, 1987.

Joseph A. McGinley, George J. Lavin, Jr. Associates, Philadelphia, Pa. and Thomas Lewry, Ernie L. Brooks, Brooks & Kushman, Southfield, Mich., for plaintiff.

Manny D. Pokotilow, Philadelphia, Pa., for Paramount Systems, Inc.

MEMORANDUM AND ORDER

EDWIN E. NAYTHONS, United States Magistrate.

*1 Defendant, Paramount Systems, Inc., has filed its motion to compel discovery of documents from the plaintiff, Manville Sales Corp., which plaintiff has refused to produce under the attorney/client privilege and the work-product doctrine. The motion seeks an order from this Court that plaintiff describe with required specificity each document that it has withheld under the attorney/client privilege or the workproduct doctrine, or to give the reasons the plaintiff claims that each document is protected.

In addition, defendant seeks this Court to review the documents in camera to separate out all documents which do not fall within the attorney/client privilege or the work-product doctrine.

Finally, and most significantly, defendant seeks an order from this Court finding that since defendant has shown a prima facie case of fraud by the plaintiff before the United States Patent and Trademark Office in obtaining the patent-in-suit, that the privileges cited are not applicable with respect to documents generated in the furtherance of the fraud.

Manville has filed this infringement action against Paramount and two individual defendants. The plaintiff is the owner by assignment of the United States Letter Patent No. 3,847,333 ('333) entitled 'Method and Apparatus for Centering a Luminaire Support.' The invention-in-suit is designed to provide a self-centering luminaire support assemby capable of traveling up and down a pole or mast. The invention is used to raise and lower highway lights and other mechanisms from atop 100'-150' poles for maintenance for replacement purposes.

Beginning in 1984, the defendant began offering for sale a self-centering Luminaire support in competition with the plaintiffs '333 mechanism. The plaintiff's complaint alleges that these offers and sales constitute willful infringement of its patent in violation of Title 35 of the United States Code. In its answer, the defendant asserts a counterclaim for a declaratory judgment pursuant to 28 U.S.C. § § 2201 and 2202 declaring the '333 patent invalid and uninfringed.

On March 20, 1987, the Honorable James McGirr Kelly denied defendant's partial motion for summary judgment when defendant challenged the patent as invalid under 35 U.S.C. § 102(b). Section 102(b) denies an inventor a patent if 'the invention was . . . described in a printed publication . . . or in public use or on sale in this country more than one year prior to the date of the application for patent in the United States.' Although the defendant need establish only one of these three events--public use, sale, or printed publication--in order to invalidate the plaintiff's patent, the defendant argued before Judge Kelly that each of these three events is present. The Court, after considering defendant's argument, found that the facts are in genuine dispute and that the matter was inappropriate for summary resolution. (At 10, Opinion Denying Partial Summary Judgment).

With regard to the defendant's first set of interrogatories, plaintiff has invoked the privilege and/or the work product doctrine in response to interrogatory Nos. 28, 50, 63(c), 65(e), 68(g), and 69, and in response to defendant's first request for production of documents speficially withregard to request nos. 2, 24, 25, 26, 28. Again defendant contends that the plaintiff offered to sell, deliver and install the invention of patent in suit during the period October-December, 1971, more than one year prior to the filing of the application on February 5, 1973 for the patent in suit in violation of 35 U.S.C. § 102(b) supra.

DISCUSSION

*2 An otherwise proper assertion of the attorney-client privilege or work-product immunity will be

vitiated by showing that the documents claimed to be protected were prepared in furtherance of a crime or fraud. See In re Grand Jury Proceedings, 604 F.2d 798, 802-03 (3d Cir. 1979). The burden falls upon the party seeking discovery on this basis to prove first, a prima facie case of criminal or fraudulent conduct, and second, that the communications were made in furtherance of the fraud. Hercules, Inc. v. Exxon Corp., 434 F.Supp. 136, 155 (D.Del. 1977).

Where the discovery dispute is grounded upon the allegation of fraud in the Patent Office, the decision of the Court of Appeals of the Federal Circuit and its predecessor courts, the Court of Claims and the Court of Customs and Patent Appeals, provide the relevant framework. A careful reading of the case law suggests that a patentee's conduct is evaluated under a different standard when the question is whether a claim of attorney-client privilege may be surmounted, rather than whether a patent may be declared unenforceable. We thus see that the standard is obviously different from that which Judge Kelly considered in the partial motion for summary judgment submitted by the defendant to declare the patent unenforceable than here where defendant seeks only to vitiate the attorney-client privilege raised by the plaintiff. In the latter instance, the Court of Appeals for the Federal Circuit has recognized that the high degree of candor imposed in patent proceedings compels the conclusion that a patent will be held unenforceable upon a showing of something less than common law fraud. See Argus Chemical Corp. v. Fiberglass-Evercoat Co., 759 F.2d 10 (Fed.Cir. 1985); J. P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1559 (Fed.Cir. 1984).

Where, as here, the question is not whether the patent is enforceable, as was raised before Judge Kelly, but whether the protective shield of the attorney/client privilege may be pierced, the patentee's conduct must be measured against traditional standard for fraud. In a patent action, that equates to a prima facie showing of (1) a knowing, willful and intentional act of misrepresentation or omission before the patent office; (2) that is material; and (3) that the Patent Office relied upon in deciding to issue the patent. Research Corp. v. Gourmets Delight Mushroom Co., 560 F.Supp. 811 (E.D.Pa. 1983). While a prima facie showing need not be such as to actually prove the disputed facts, it must be such as to subject the opposing party to the risk of non-persuasion if the evidence as to the disputed fact is left unrebutted. Hercules, Inc. v. Exxon Cor., 434 F.Supp. at 155 (Quoting Dupland Corp. v. Dearing Milliken, Inc. 540 F.2d 1215 (4th Cir. 1976).

Once a showing of fraudulent conduct is made, it is then necessary to determine whether the documents were prepared in furtherance of the fraud. As Judge Wright explained in Hercules Inc., supra,

> Communications made before the fact of or during the commission of a fraud are not protected, since to allow protection would permit an attorney to be a principal or accessory to a fraud without fear of discovery and would permit the client to permit the fraud with the aid of legal advice beforehand. Communications after the fact are still protected, however, since one of the primary purposes of the attorney-client privilege is to allow a consultation in the interest of establishing a legal defense. Burlington Industries v. Exxon Corp. (61 F.R.D. 26 (D.Md. 1974)); Duplan Corp. v. Dearing Milliken, Inc., 397 F.Supp. 1146, 1172.
> *3 Hercules, Inc., 434 F.Supp. at 155.

In resolving disputes of this nature, Courts often call for in camera inspection of the documents in question. There is a divergence of opinion, however, with respect to whether the allegedly privileged communications may be considered in the determination of whether a prima facie case of fraud has been established. Compare In re Berkley Co., 629 F.2d 548, 533, n.9 (8th Cir. 1980); (privileged documents may be considered in the fraud analysis) and Duplan Corp. v. Dearing Milliken, Inc., 397 F.Supp. 1146, 1194-95 (D.S.C. 1974) with United States v. Schewfelt, 455 F.2d 836, 840 (9th Cir. 1972) (independent evidence of fraud must be adduced before privileged documents may be ordered), cert. denied, 406 U.S. 944 (1972). That issue need not be resolved at present since it is clear in this United States Magistrate's view from the independent evidence adduced by the defendant that a prima facie case of fraud has been shown [FN1]

PRIMA FACIE EVIDENCE OF FRAUD

During the summer and fall of 1971, the plaintiff installed a lowering device for the Wyoming State Highway Department at the Fort Steel Rest Area in Rawlings, Wyoming. After installation of the lowering device, the State Highway Department informed the plaintiff that the lowering device was not performing properly.

Exhibit E attached to defendant's memorandum is an internal memo of the Holophane Co., Inc. (a subsidiary of the plaintiff), dated October 22, 1971, addressed to Darryl Sullivan, the inventor's supervisor, which specifically stated that the customer was unhappy with the plaintiff's lowering

device, and that the customer had asked for modification so that unit would track better on sided (non-round) poles. The memorandum stated that a design for lowering devices is being done now but requests by return mail some sort of drawing showing a modification for a sided pole.

Exhibit F shows another internal memorandum of the plaintiff dated October 29, 1971 which stated the plaintiff's experience on the Rawlings job has enabled the plaintiff to redesign the lowering device tracking mechanism so it works properly with a multisided pole. The memorandum stated that this modification will shortly be installed on the pole in Rawlings.

On October 29, 1971, Robert D. Zeller, the inventor of the patent-in-suit, wrote to Charles Wilson, the state bridge engineer for the Wyoming State Highway Department, offering specification drawings of a modified lowering device which was being supplied for the Fort Steel Rest Area. Among the drawings submitted to the Wyoming State Highway Department was drawing D-3063. D-3063 demonstrated by Exhibit H showed a plan and side views of plaintiff's new lowering device being offered to replace the previous lowering device which did not satisfactorily meet the customer's requirements.

The patent-in-suit is included as Exhibit I. A comparison between Exhibit H, a drawing of the device supplied to the State of Wyoming, during 1971 and figures 1 and 2 of the patent-in-suit, Exhibit I, reveals that the device supplied to the State of Wyoming during November-December 1971 is practically identical, except for some minor, non-essential changes, to the invention shown in the patent-in-suit in Figures 1 and 2 and operates in the same fashion. In fact, the inventor, Mr. Zeller has admitted that the centering mechanism supplied to the state of Wyoming during 1971, as shown by Exhibit D-32, Exhibit H, was like the centering mechanism of the patent-in-suit. See Exhibit J, Transcript of Zeller's deposition, p. 72, lines 10-13. Further, Mr. Zeller admitted on p. 72, line 20-21, that he thinks the centering mechanism of the lowering device of Drawing D-3063 was used on the job in Rawlings, Wyoming in later November or early December 1971.

*4 It should also be noted that Charles Wilson of the Wyoming State Highway Department, in his affidavit, included in defendant's memorandum as Exhibit L stated that it is his understanding that the lowering device installed during November-December 1971 was installed to complete the sale of the lowering device of the State of Wyoming on a public contract. Mr. Wilson stated,

> 'It was my understanding that the lowering device shown in Exhibit F was installed to complete the sale of the lowering device to the State of Wyoming on a public contract. There was no statement in our file nor do I recall any statement by Holophane, Inc. that the lowering device installed was experimental. I do not recall any suggestion that the lowering device was considered to be experimental by Holophane Co., Inc.' (Emphasis Added).

The evidence thus indicates that the device of the invention was supplied to the State of Wyoming to replace a defective device provided by the plaintiff and prima facie to complete the sale of the device under a public contract during 1971. Further, there is prima facie evidence that the inventor and the plaintiff, the assignee of the patent-in-suit, did not indicate in any way that the equipment was being supplied on an experimental basis. It is clear for the purposes of the prima facie evidence test that the device was placed on sale and delivered and installed more than one year prior to the February 5, 1973 application date for the patent-in-suit.

By its nature, a patent is affected with a strong public interest. Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806, 816. It is both a privilege recognized under our Constitution and 'an exception to the general rule against monopolies.' Id. Hence, because of the patent's far-reaching social and economic implications, the public has 'a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct.' Id. As a consequence, the case law and the Rules of Practice in Patent Cases require patent attorneys and applicants to exercise the highest degree of candor and good faith in their dealings with the Patent and Trademark Office. Kingsland v. Dorsey, 388 U.S. 318, 319 (1949); 37 C.F.R. 1.56 (1982).

The protection of the public interest is unquestionably at the core of the patent attorney's duty of candor toward the Patent and Trademark Office. The attorney/client privilege is not, however, inherently detrimental to federal patent policy and the protection of the public interest. In Re Natta, 410 F.2d 187, 190-91, 161 U.S.P.Q. 389, 391 (3d Cir. 1969); Natta v. Hogan, 392 F.2d 686, 691-92 (10th Cir. 1968); Collins & Aikman Corp. v. J.P. Stevens

& Co., 219, 220-221 (D.S.C. 1971). The duty of candor largely equates with a duty of disclosure. The purpose of the attorney-client privilege on the other hand, is to facilitate the administration of justice by encouraging the free and open exchange of information between attorney and client. The duty of candor and the privilege thus serve differing interests, more often than not, however, the freedom of consultation fostered by the privilege aids the patent attorney in satisfying his duty of full disclosure to the Patent and Trademark Office. Recent decisions, therefore, have uniformly recognized the applicability of the attorney/client privilege to patent proceedings. See Burlington Industries v. Exxon Corp., 65 F.R.D. 26, 34-35 (D.Md. 1974).

***5** As described in detail above, it is this Court's view that the three requirements for showing a prima facie case of fraud by the plaintiff before the United States Patent and Trademark Office have been met.

The inventor of the device for the patent-in-suit knowingly misrepresented and omitted a material fact in not informing the Office that the device of the invention had been offered to, delivered to, and installed for the Wyoming State Highway Department during November-December, 1971 more than one year prior to the filing of the application for the patent-in-suit on February 5, 1973. The device of the invention was delivered to the Department and installed at the Fort Steel Rest Area to replace a defective lowering device with which the customer was not satisfied. This was done to complete the sale of the lowering device under a public contract. The customer was never informed by the plaintiff that the device was experimental, according to the affidavit of Mr. Wilson, or delivered or installed for any other purpose than to replace a faulty unit which had been offered for sale and not accepted and to complete the sale of it by the plaintiff under a public contract with the patented product.

Furthermore, their misrepresentation and omission is certainly 'material.' If, having been presented information regarding the transaction, the examiner had determined the transaction indeed constituted an offer for sale or a sale of the patented device within one year prior to the filing of the application for the patent, the patent may have clearly been barred under 35 U.S.C. 102(d). Clearly, the Patent office relied upon the misrepresentation and omission in deciding to issue the patent. An offer for sale or sale prior to one year before the filing of the application would have prevented issue of the patent.

In order to meet the burden posed upon the defendant, defendant must and has shown that had the Examiner known of the misrepresentation and omission, he would have rejected the applicant's claims. American Optical Corp. v. United States, 179 U.S.P.Q. 682 (Ct. Cl. 1973).

No one can tell with certainty what would have happened if the applicant had dealt fairly and openly with the Patent Office. But the fact remains that the applicant did withhold relevant facts. Which side in this litigation is to sustain a detriment from the contract? It is appropriate that it be Manville who sustains it. Any other rule would fail adequately to discourage conduct of this sort merely because of the circumstance, which must be present in many cases, that it turns out to be impracticable to ascertain what the Examiner, who did not know the true facts, would have done if he had known them.

It may be unduly harsh to characterize Manville's conduct here as fraud. Conduct which has been so labeled in the decisions has, by and large, been more reprehensible than this. But at the least, it was conduct which was lacking in candor. It was intentional nondisclosure of relevant data which might have affected the outcome of the patent application.

PLAINTIFF'S CONTENTIONS

***6** Plaintiff continuously argues that defendant's motion is based on a 'rehash of the same arguments which already have been considered or rejected by the Court in Paramount's Motion for Partial Summary Judgment.' While it is correct that Paramount is making a similar argument as already indicated, the requirements for prima facie showing of fraud are less than the requirements for proving that there is no dispute as to the facts relating to the 'on sale' bar as in a motion for summary judgment wherein the non-movant must be given the benefits of any doubts. As stated by the Court in Union Carbide Company v. Dow Chemical Co., 619 F.Supp. 1036, 1052, 'a prima facie showing need not be such as to actually prove the disputed facts. It must be only such as to subject opposing party to the risk of nonpersuasion if the evidence as to the disputed fact is left unrebutted.' Consequently, we reemphasize in ruling that a prima facie case of fraud has been shown does not and would not be making a judgment that a fraud has been committed.

Plaintiff likewise contends with forceful argument that Holophane's conduct was classic 'experimental use.' The experimental use doctrine in patent law has

been explained in Paeco, Inc. v. Applied Mouldings, Inc., 562 F.2d 870 (3d Cir. 1977) as follows:

> That doctrine allows an inventor a reasonable period of experimentation wherein he may perfect his ideas, provided that the inventor truly has utilized the public use and sale to that laudable end, and not as a competitive tool to exploit his invention and gain an advantage over others. 562 F.2d at 874.

There is no evidence that plaintiff placed any restriction on the State of Wyoming's use of the units in question. The absence of any restriction by the patentee on the uses of a patented invention is indicative of a non-experimental purpose. Egbert v. Lippman, 104 U.S. 333, 336, 26 L.Ed. 755 (1881). To avoid the on sale bar, inventor must show that the transferee lacked authority to use the invention or exploit its commercial value. But where an inventor sells or delivers an invention to another without any enforceable obligation for the other to hold the invention for experimental purposes only, the unrestricted sale or delivery will invalidate the patent. Kock v. Quaker Oats Co., 681 F.2d 649, 655 (9th Cir. 1982), cert. denied, 103 S.Ct. 787, 74 L.Ed.2d 994 (1983).

Another factor that is indicative, prima facie, of non-expermimental purpose is the failure to require test reports. The evidence in this case at this point demonstrates that Manville did not require the State of Wyoming to report back to it any results of its use of the units in question. Where a person has authority to use an invention commercially or sell to others without any duty to experiment further, there is a sale within the meaning of § 102(b) and the experiment exception does not apply. Kock v. Quaker Oats Co., 681 F.2d at 656. Accordingly the following Order is hereby entered.

ORDER

*7 NOW, this 11th day of September, 1987, with respect to Interrogatory Nos. 28, 50, 63(c), 65(e), 68(g), and 69 as well as the request for production of documents Nos. 2, 24, 25, 26, and 28, it is hereby ORDERED that within twenty (20) days from the date of receipt of this Order, counsel for plaintiff shall specifically identify the nature of the privilege which is being claimed and the privileges being asserted in connection with a claim defense governed by state law, and indicating the state's privilege rule being invoked and the following information shall be provided:

A. For the documents in question
1. the type of documents;
2. the general subject matter of the documents;
3. the date of the document;
4. Such other information as is sufficient to identify the document for a subpoena duces tecum, including, where appropriate, the author of the document, the addressee of the document, and where not apparent, the relationship of the author and addressee to each other.

B. With respect to the interrogatories mentioned above:
1. the name of the person making the communication and the names of the persons present while the communication was made and where not apparent, the relationship of the persons present to the person making the communication;
2. the date and place of communication;
3. the general subject matter of the communication.

Plaintiff shall further be required to submit to this United States Magistrate all of the documents which it has withheld from the defendant on the grounds of attorney/client privilege or work-product doctrine for in camera inspection by the court within thirty (30) days from the date of receipt of this Order.

Failure of the plaintiff to comply with this Order without good cause shall result in the Court's entering the appropriate sanctions precluding plaintiff from introducing relevant and pertinent evidence at the trial of the case.

> FN1 It must be emphasized that this Court today decides only that there is a prima facie showing of fraud on the Patent Office and not that there has been actual fraud. The Court's assessment of the lateral issue must await trial on all of the evidence as set forth in Judge Kelly's opinion in denying defendant's motion for partial summary judgment.

Not Reported in F.Supp., 1987 WL 16888 (E.D.Pa.), 9 Fed.R.Serv.3d 152

END OF DOCUMENT